PATIENT-CENTERED OUTCOMES IN EMERGENCY DEPARTMENTS AND ADULT SICKLE CELL INFUSION CENTERS

by

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ABSTRACT

BACKGROUND: Adults with sickle cell disease (SCD) frequently experience acute painful vaso-occlusive crises (VOC), which are the most common indication for hospitalizations and emergency department (ED) visits. As an alternative to ED care, an infusion center (IC) is a comprehensive model of acute care delivery and may provide care that is more patient-centered. The goal of this dissertation was to evaluate the psychometric properties of a satisfaction scale and to investigate the association between the setting of care and patient-centered outcomes - patient satisfaction with pain management and patients' perception of safety after the treatment of an acute VOC.

METHODS: A cross-sectional analysis was conducted using first time visits of adult patients with SCD who were enrolled in a multisite prospective cohort study. Surveys were administered to patients within 72 hours after the visit. In the first study, I conducted an exploratory factor analysis (EFA), tested for construct validity, and internal consistency reliability for the **P**atient **S**atisfaction with **P**ain Management in Adults with **S**CD (PSPS) scale. In the second study, I used structural equation modeling to examine the association between the setting of care and patient satisfaction. In the third study, I fit regression models for patients' perception of safety as a function of setting of care.

RESULTS: EFA revealed a single factor of patient satisfaction with pain management that was represented by 15 survey items. Correlations between the mean satisfaction score and two validated safety measures demonstrated construct validity

and the scale had a high Cronbach's α (0.97). Receiving care at an IC is statistically significantly associated with higher levels of satisfaction compared to receiving care at an ED. Relative to the ED, patients who received care at an IC were significantly less likely to experience lower perceptions of overall patient safety, less likely to perceive medication errors and mistakes by nurses, and had fewer numbers of specific safety concerns.

CONCLUSIONS: The IC provides care that is more patient-centered compared to the ED for treating acute VOC. Further studies are needed to control for system-level factors that may affect the relationship between the setting of care and patient-centered outcomes.

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CHAPTER 1. INTEGRATIVE CHAPTER

1.1 Background

Sickle cell disease (SCD) is the most common inherited blood disorder in the United States (US) causing significant morbidity and early mortality. In the US, it has been estimated that about 100,000 individuals live with SCD, predominately affecting African Americans (1:365) and Hispanics (1:16,300). The prevalence of SCD varies by state, which makes it challenging to deliver healthcare to subpopulations with SCD. [1] Adults living with SCD often experience chronic anemia, pain, and a number of complications. Acute painful vaso-occlusive crises (VOC) are the hallmark of SCD: they are a severe form of frequent acute pain episodes that could be unmanageable and unpredictable, affecting mainly the long bones and joints (e.g. extremities, chest, and back). Acute VOC may also affect other parts of the body, leading to a number of complications including acute chest syndrome, multisystem organ failure, acute stroke, acute splenic sequestration, acute kidney injury, hepatobiliary complications, and priapism in men. [2, 3] Other complications of SCD include chronic pain, pulmonary hypertension, retinopathy, avascular necrosis, nephropathy, and leg ulcers. [2, 4] Thus, adults living with SCD experience a life-long illness with a wide range of serious and severe forms of impairments.

As a result of this life-long illness and debilitating symptoms, life expectancy has been reduced by 30 years in adults with sickle cell anemia (SCA), which is the most common and severe form of SCD, compared to the African American general population in the US and roughly 50% of patients with SCA survive beyond the fifth decade. [5] The mean age at death for SCD is 39 years according to the most recent data reported from the CDC. [1] The median age at death for males and females with SCD is 38 years and 42 years, respectively. [6] Corresponding to the emergence of

universal newborn screening, [7] penicillin prophylaxis, [8] use of conjugated pneumococcal vaccination, [9] provision of disease-modifying treatments such as hydroxyurea, [10] and transcranial Doppler screening to identify strokes, [11] age at death has markedly been shifted to death at older ages. [5] The shift in mortality age creates a challenge of increased demand for healthcare for adults including increased morbidities that accompany this disease.

Despite the improved survival among children, improvements in survival have not been seen among adults during the same time that children and adolescent survival has improved, which may be attributable to lack of comprehensive care and increased rates of hospitalizations and readmissions. [6, 12-14] Adults living with SCD also suffer from reduced health-related quality of life compared to the general population and at a level comparable to patients with chronic hemodialysis. [15] Additionally, there is high prevalence of unemployment among adults living with SCD ranging between 40% and 60% because of the disability that SCD causes. [16] Most importantly, several gaps exist in providing high quality of care for adults with SCD in an era where extensive improvements in quality of care have been made in other genetic and chronic illnesses such as cystic fibrosis and hemophilia. [12]

1.2 Problem Statement and Gaps in the Literature

In alignment with the IOM aims for improvement of care, patients should receive care that is safe, effective, patient-centered, timely, efficient, and equitable. Patient-centered care is defined as "providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions." [17] Patient-centered care may improve quality of care and specifically, improve safety and effectiveness of care. [18, 19] While there is no

best way to measure patient-centeredness, this may be reflected by focusing on outcomes that are meaningful and important to patients, such as patient satisfaction with pain management and patients' perception of safety, as a way to ensure that patient-centered care is achieved. [20]

Patient satisfaction with pain management is an important measure for assessing the quality of care and reflective of patient-centered care. The concept of patient satisfaction with pain management in adults with SCD that are being treated for an acute VOC in the acute care setting has not been rigorously and methodologically structured including validity and reliability assessments. Standardized satisfaction scales that are available for other populations are not designed to capture aspects of pain management that are specific to adults with SCD nor are they specific to the acute care setting. There has been a lack of valid and reliable instruments that allow patients with SCD to self-assess their satisfaction with pain management after being treated for an acute VOC in the acute care setting. Further instruments to assess the extent of agreement between a patient's expectation of ideal care and perception of care received ("patient satisfaction" defined) [20, 21] accurately are needed not only to capture patients' evaluation of their care but to help in achieving patient-centeredness using a patient-centered approach.

Even though adults with SCD mostly manage their pain at home, [22] acute VOC is the most common indication for emergency department (ED) utilization and hospital admissions. [13, 23] Adults with SCD are often dissatisfied with the quality of pain management in the ED for the treatment of acute VOC. [24, 25] Pain management for an acute VOC in the ED is often marked with long delays and inadequate management due to ED overcrowding and ED clinicians' lack of knowledge and expertise on how to manage these pain episodes. [24, 26] Patients

have noted several issues with their pain management that are related to their interactions with their providers, such as negative provider attitudes, providers' lack of sympathy, perception of stigma and drug seeking behavior, and not sufficiently being involved in making care decisions. [24, 25] The ED is an important setting for managing acute pain but also a challenging one for providing patient-centered care for adults with SCD. Therefore, it is important to identify and adopt models of care for acute pain management that focus on providing patient-centered care to improve the quality of care for adults with SCD. [12, 27]

As an alternative to ED care, an *infusion center* (IC) or a *day hospital* is an outpatient hospital-based facility that specializes in treating pain in adults with SCD, provides comprehensive services and continuity of care, and may provide care that is more patient-centered. Currently, there is a paucity of ICs in the US, which are located primarily in urban areas and are less likely to be networked nationwide. [12] Thus, the lack of availability of ICs and access to these facilities are one of the issues in providing care for adults with SCD. Although studies have shown that ICs provide timely pain management, reduce hospital admissions, and increase patient satisfaction levels, [28-33] there has been a lack of studies that examine the associations between the acute care settings (ED and IC) and patient-centered outcomes. Only one study conducted a decade ago in a single institution in the US studied patient satisfaction with care between patients receiving care at the ED and IC. Aisiku et al. reported higher levels of satisfaction in the IC in contrast to the ED with regards to global satisfaction, technical quality, accessibility and convenience, and financial aspects of care. No statistically significant differences were found in interpersonal manner, communication, and time spent with doctor. [28]

Patients' perception of safety in the acute care setting may also reflect patient-centered care and may be associated with patient satisfaction. [34] Recently, based on discussions with the Patient-Centered Outcomes Research Institute (PCORI) patient advisory counsel of adults with SCD, the issue of safety has been raised as being concerning in the ED given the lack of provider experience and knowledge to manage patients with SCD. Yet, patient safety has not been investigated in adults with SCD neither have associations with the acute care setting ever been explored.

Given the gaps in the literature on what may contribute to patient-centered outcomes with respect to the ED and IC, the overall goal of this dissertation is to examine the associations between the setting of care (ED or IC) and patient-centered outcomes including patient satisfaction with pain management and patients' perception of safety after the treatment of an acute VOC.

1.3 Specific Aims

The following specific aims and hypotheses will be addressed:

Aim 1 will evaluate the psychometric properties of the **P**atient **S**atisfaction with **P**ain Management in Adults with **S**CD (PSPS) scale designed to assess patient satisfaction after treatment for acute VOC in the acute care setting. This is a descriptive study to evaluate the validity and reliability of an instrument that has been developed by experts in sickle cell research to assess patient satisfaction with pain management after a recent acute care visit in the ED and IC for the treatment of an acute VOC.

Aim 2 will investigate the association between care provided in the ED or IC and adults' patient satisfaction with pain management for the treatment of acute VOC. We hypothesized that receiving care at an IC for the treatment of acute VOC will be

associated with higher levels of satisfaction with pain management compared to receiving care at an ED for adults with SCD.

Aim 3 will examine the association between care provided in the ED or IC and patients' perception of safety during an acute care visit for the treatment of acute VOC among adults with SCD. We hypothesized the following:

3.1 Patients who receive care in the IC will have lower odds of perceiving lower levels of overall patient safety relative to patients who receive care in the ED.

3.2 Patients who receive care in the IC will have lower odds of perceiving each of eight specific safety concerns compared to patients who receive care in the ED. These specific safety concerns are: falling and being injured, medication errors, problems with medical equipment, mistakes by nurses, mistakes by physicians, being mistaken for another patient, wrong test/procedure, and misdiagnosis.

3.3 Patients who receive care in the IC will more likely report fewer numbers of perceived specific safety concerns compared to patient who receive care in the ED.

1.4 Conceptual Framework

My hypotheses were based on the Coyle and Battles' modified Donabedian's Structure – Process – Outcome (SPO) model for assessing the quality of medical care. [35] (Figure 1) The traditional Donabedian framework is made up of three components to measure the quality of medical care: structure, process, and outcome. Structure measures reflect the attributes of the clinical setting (e.g. facilities, equipment, and staff to patient ratio). Process measures are informative on how care is being delivered and whether certain services of care are provided or not (e.g. communication between a patient and physician and physician prescribing an

appropriate medication). Outcome measures are the effect or result of care on health status (e.g. improved patient satisfaction and reduced mortality). Donabedian suggests that these three components are interrelated; thus, structure may cause process and process may cause outcome. However, establishing this relationship may be complex and hard to demonstrate. [36] Coyle and Battles suggested incorporating pertinent antecedents of medical care into outcome assessment. Antecedents may include patient characteristics, such as genetics and socio-demographics, and health attitudes that may affect outcomes. [35]

For **Aim 1**, my emphasis will be on providing evidence for validity and reliability of the outcome of patient satisfaction with pain management. After that has been established, for **Aim 2**, I will focus on the association of structure (ED vs. IC) with outcome (patient satisfaction with pain management) controlling for important confounders that may influence this relationship. For **Aim 3**, I will focus on the association of structure (ED vs. IC) with outcome (patients' perception of safety) controlling for important confounders that may influence this relationship.

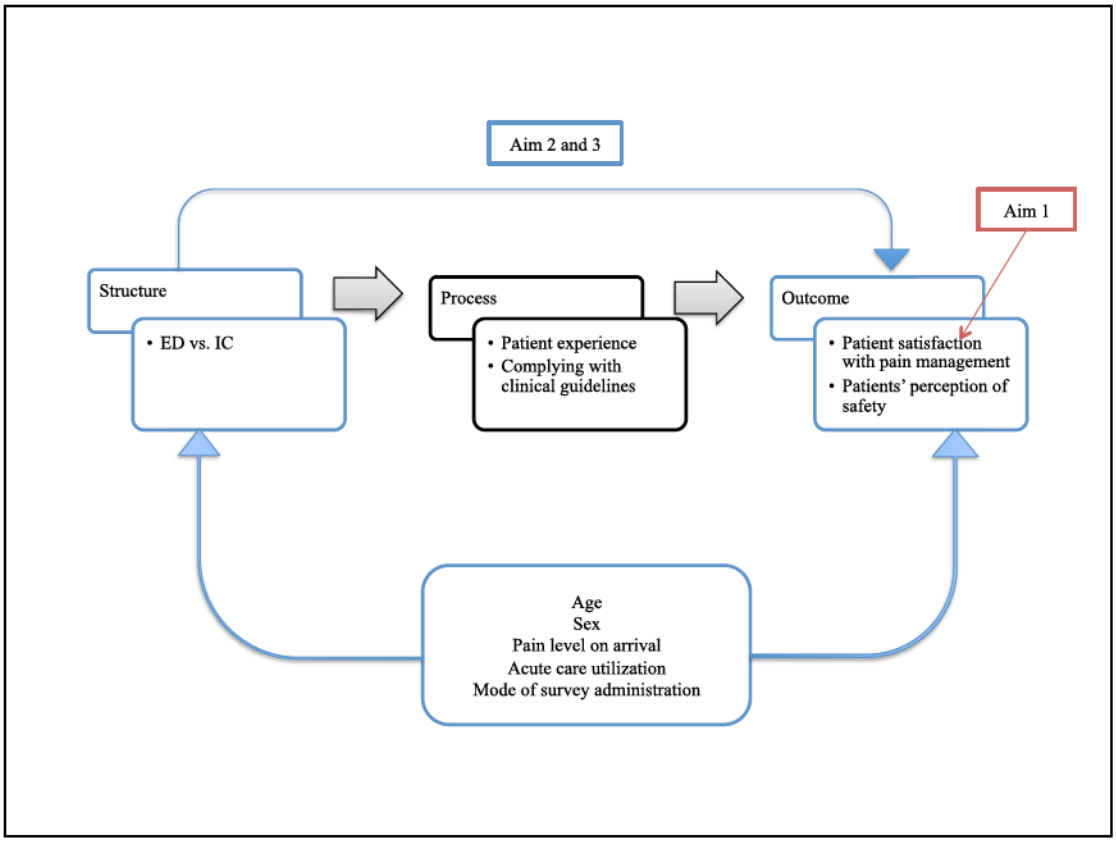


Figure 1.1 Conceptual framework of the Coyle and Battles' modified Donabedian's Structure – Process – Outcome (SPO) model to examine the association between the setting of care (ED or IC) and patient-centered outcomes

1.5 Dissertation Organization

This dissertation is organized based on the three-manuscript format and is divided into five chapters. Chapter 1 provides the introduction of the dissertation including background on SCD, problem statement and gaps in the literature, specific aims and hypotheses, and conceptual framework. Chapter 2 (Manuscript 1) provides preliminary evidence on the validity and reliability of the patient satisfaction with pain management in adults with SCD (the PSPS) scale. Chapter 3 (Manuscript 2) provides results on the association between care provided in the ED or IC and patient satisfaction with pain management. Chapter 4 (Manuscript 3) provides results on the association between care provided in the ED or IC and patients' perception of safety.

Chapter 5 is a summary of the principal findings and a discussion of the policy and practice implications of the principal findings of this dissertation.

CHAPTER 2. EVALUATING PSYCHOMETRIC PROPERTIES OF A SCALE TO ASSESS PATIENT SATISFACTION WITH PAIN MANAGEMENT OF SICKLE CELL ACUTE VASO-OCCLUSIVE CRISES IN THE ACUTE CARE SETTING

2.1 Abstract

Background: Adults with sickle cell disease (SCD) are often dissatisfied with the quality of pain management of acute vaso-occlusive crises (VOC), which is the most common indication for acute care utilization in this population. General satisfaction scales do not adequately address aspects of pain management that are specific to this population or to the acute care setting [Emergency department (ED) or sickle cell infusion center (IC)]. The objective of this study was to evaluate the psychometric properties of the **P**atient **S**atisfaction with **P**ain Management in Adults with **S**CD (PSPS) scale designed to assess patient satisfaction after treatment for acute VOC in the acute care setting.

Methods: An instrument was developed using an extensive review of the literature and expert consensus to encompass aspects of care related to acute pain management in adults with SCD. To evaluate validity and reliability, we conducted a cross-sectional analysis of first time visits of adult patients (>18 years) with SCD from April 2015 to December 2016, recruited from four sites in the United States (US) as part of a larger study**.** We surveyed participants within 72 hours after a visit to the ED or IC for an acute VOC. We conducted exploratory factor analysis (EFA), investigated the construct validity by testing the correlation between each of two validated safety measures and the PSPS mean score, and calculated internal consistency using Cronbach's alpha (α).

Results: A total of 207 patients with complete survey responses were included in the analysis; the response rate was 56%. EFA revealed a single factor of patient satisfaction with pain management that was represented by 15 survey items. All factor loadings ranged between 0.64 and 0.90 and were statistically significant. The mean PSPS score was positively correlated with a safety measure of global safety in the acute care setting (Spearman's rho = 0.63; $p < 0.001$) and inversely correlated with the number of concerns patients reported during their stay (r = -0.47; $p < 0.001$). The instrument also had high reliability (Cronbach's $\alpha = 0.97$).

Conclusions: The PSPS, an instrument for assessing patient satisfaction with pain management in adults with SCD after the treatment of an acute VOC in the acute care setting, demonstrates preliminary evidence of validity and reliability. The PSPS shows promise for use in quality improvement intervention studies in the acute care setting to achieve patient-centered care in adults with SCD. Further research is needed to assess sensitivity to change in a longitudinal analysis.

Keywords: Construct validity; factor analysis; pain management; patient-centered care; patient satisfaction; psychometrics; reliability; sickle cell disease

Running Title: Psychometrics of the Patient Satisfaction with Pain Management Scale

2.2 Background

Sickle cell disease (SCD) is the most common inherited blood disorder in the United States (US), causing significant morbidity and early mortality. [1] Adults with SCD generally experience acute painful vaso-occlusive crises (VOC), which are the most common indication for hospitalizations and emergency department (ED) utilization. [13, 37] Adults with SCD are often dissatisfied with the quality of pain management of acute VOC: they often report negative provider attitudes and poor provider knowledge, and experience delays in medication administration. [24, 26]

Patient satisfaction with pain management in the ED and other acute care settings is a concept that encompasses several closely interrelated aspects of care. Patient satisfaction with interpersonal interactions and communication with ED providers, including doctors and nurses, have been shown to be associated with overall ED satisfaction. [38, 39] Patients' perception of ED provider technical skills, wait times, and pain medication provision reflect aspects of care inclusive of satisfaction with pain management in the ED. [38, 40] Specifically in adults with SCD, the quality of patients' interactions with clinical providers may be related to delaying seeking care, self-discharging from the hospital, and choosing to manage pain at home. [41, 42] However, it might be difficult for patients to view those aspects of care as distinct underlying constructs of patient satisfaction given the interconnectivity of those aspects when it comes to treating pain episodes.

Standardized satisfaction scales are not designed to address issues with pain management specific to this population or to the acute care setting including the ED and infusion centers (IC), which is an outpatient hospital-based center that provides comprehensive and coordinated care for pain management in adults with SCD. There has been a lack of valid and reliable instruments that allow patients with SCD to self-

assess their satisfaction with pain management after being treated for an acute VOC in the acute care setting. We found one study that developed a patient satisfaction scale in adults with SCD to assess patient satisfaction with services provided in a non-urgent sickle cell unit in Jamaica. This study provided evidence of preliminary validity and reliability of the Patient Satisfaction Questionnaire – Sickle Cell Unit (PSQ-SCU) supporting a four-subscale structure including nurses, appointments, facilities, and social worker. [43] However, these subscales do not reflect satisfaction with pain management nor do they reflect care provided in the acute care setting. Thus, no scale was found to be inclusive of aspects of pain management in adults with SCD in the acute care setting. Further instruments to assess the extent of agreement between a patient's expectation of ideal care and perception of care received ("patient satisfaction" defined) [20, 21] accurately are needed not only to capture patients' evaluation of their care but to help in achieving patient-centeredness using a patient-centered approach.

Therefore, instruments with valid and reliable properties should be developed with a focus on aspects of care related to pain management in adults with SCD being treated for an acute VOC in the acute care setting. Our objective is to evaluate the psychometric properties of the **P**atient **S**atisfaction with **P**ain Management in Adults with **S**CD (PSPS) scale designed to assess patient satisfaction with pain management after the treatment of an acute VOC in the acute care setting.

2.3 Methods

Study Design and Study Setting

As part of a longitudinal prospective cohort study (the ESCAPED study; Examining Sickle Cell Acute Pain in the Emergency vs. Day Hospital), a cross-

sectional analysis of first time visits from April 2015 to December 2016 was conducted. The main purpose of the ESCAPED study was to compare patient-centered outcomes for patients being treated for an uncomplicated VOC in the ED and IC. In the ESCAPED study, patients were recruited from four sites in four cities in the US: Baltimore, Maryland; Cleveland, Ohio; Milwaukee, Wisconsin; and Baton Rouge, Louisiana. Each site had both an ED and an IC. Sites were considered geographically and clinically diverse with a goal to represent a heterogeneous sample of patients. ICs varied among sites in the following: (1) all sites were academic settings except for one site –Baton Rouge, which was a community-based private practice; (2) two of the ICs were single-focused centers and two were shared ICs; and (3) all ICs operated on average eight to ten hours on the weekdays and not all ICs were open during the weekends.

Study Population

Patients were initially enrolled in the ESCAPED study if they were 18 years or older, had a confirmed diagnosis of SCD, lived within 60 miles of a study site, and received regular care at a study site. Patients were excluded from enrollment into the study if their SCD was well-controlled on chronic transfusions with no episodes of acute VOC in the two years before enrollment, unable or unwilling to provide informed consent, or pregnant. Patients were enrolled during regular outpatient clinic visits, provided written informed consent, and were asked to remain in the cohort for 18 months. Patients in this study may have also utilized EDs other than these four institutions, which allowed the capture of more general experiences of care in a broad range of ED settings. Surveys were administered to patients after each acute care visit until the end of the 18-month follow-up period or loss to follow-up. (See Appendix A for survey instrument)

In this study, we only included patients who had complete responses to the survey administered after their first acute care visit. Included visits were for the treatment of an uncomplicated acute VOC, defined as an acute episode of pain with no other known cause that requires parenteral therapy for pain relief. While there is no strict rule for sample size requirement for factor analysis, we considered both the total number of participants and participant to survey item ratio due to their interaction with one another. [44] A number of participants of at least 200 were considered adequate along with a suggested participant to survey item ratio of 10:1 based on previous studies. [45] The Institutional Review Boards at all participating sites approved the study.

Scale Development

The satisfaction scale was developed in a number of steps. First, the research team conducted a literature review of quantitative and qualitative studies in patients with SCD to identify aspects of pain management that are important to patients. [24, 25, 46-48] Several aspect of pain management were identified including: 1) aspects of pain delivery and pain control (assessment of pain, timeliness of medication treatment, pain medication at home, etc.); 2) interpersonal aspects of care (ability of physicians and nurses to communicate with patients, be sympathetic, involve patients in decision-making, etc.); 3) stigmatization of patients with SCD, and 4) general perception of quality of care. Second, research team members that are experts in sickle cell research searched for and evaluated validated satisfaction and satisfaction-related instruments that exist in general populations that are being treated for pain in various clinical settings. [49-54] None of the identified instruments were comprehensive of aspects of pain management or specific to the acute care setting. Third, a number of survey items that were thought to be reflective of aspects of pain

management in adults with SCD were selected from those existent instruments. A total of 23 survey items were selected and reviewed by the research team. (Figure 2.1)

All 23 items came from previously validated surveys (or were adapted from those surveys) except for two items that were newly developed. [49-53] The two items that were newly developed were thought to be important to include based on group consensus and were not presented in other existent instruments. These new items were 'The provider ensured that you had enough pain medication to manage your pain at home' and 'Bringing someone with me when I am in the ED/IC helps improve the quality of care I receive'. Only a few items were minimally adapted such as replacing the word 'ED physicians' with 'physicians' so that the survey would be applicable to patients receiving care at an IC.

Fourth, all 23 items were discussed during the annual Patient-Centered Outcome Research Initiative (PCORI) study meeting of the ESCAPED study. Feedback from research team members including experts in hematology care and SCD research, community-based organization leaders that promote advocacy and healthcare delivery for SCD, and an insurer representative was incorporated into eliminating 8 items that were thought to be redundant or included words that were confusing. Elimination of those items also supported the practicality and feasibility for future applications and the reduction of respondent burden due to the extent of pain the population of SCD experiences. The process undertaken helped establish face and content validity of the final scale, called the Patient Satisfaction with Pain Management in Adults with SCD (PSPS), which included 15 items.

Patients reported the extent of agreement or disagreement during their recent acute care visit with the following 15 items: 1) The staff adequately assessed your pain, 2) You received treatment in a timely manner, 3) The doctor seemed to know

just what to do for my problem, 4) Your pain was adequately controlled, 5) The provider ensured that the patient had enough medication to manage pain at home, 6) You were satisfied with the communication with the nurses, 7) Your nurse believed your reports about your pain, 8) You were satisfied with the communication with the doctors, 9) Your doctor believed your reports about your pain, 10) The doctor seemed warm and friendly to me, 11) I really felt understood by my doctor, 12) This is a doctor I would trust with my life, 13) The doctor has relieved my worries about my illness, 14) During your visit, you were allowed to participate in decisions about your pain treatment as much as you wanted to, and 15) Overall, you are satisfied with the quality of care you received. All 15 items were positively worded and were scored on a 7-point Likert scale from *very strongly disagree* (1) to *very strongly agree* (7) similar to the response options from previously published scales. [50, 52] Higher scores on each item indicated higher satisfaction levels.

Data Collection

At enrollment, participants filled out a survey to collect demographic and medical information. Electronic medical records were reviewed to confirm existing disease complications. To ensure that visits outside the ED study site were captured, participants were contacted on a monthly basis and where available statewide health information exchanges were queried. After an eligible acute care visit, trained research coordinators administered the PSPS scale within 72 hours. A period of 72 hours was set to capture experiences more robustly and to minimize recall bias. [55] The survey was administered in different modalities to accommodate patient preferences and to maximize response rates. [56] Surveys were interview-administered by phone or self-administered to participants. When self-administered, participants either completed the survey in-person before leaving the ED or IC using a

paper-pencil or by computer where a link was sent via email. Patients were compensated $25 for participation in the study. [57] Patients who did not respond to the survey were either too sick, refused to participate, or were not contacted within the 72 hour window after their acute care visit.

The dependent (outcome) variable was patients' mean score on the PSPS, calculated by adding all patients' responses and then dividing it by the number of survey questions answered. The main independent variables for this study were patients' perception of patient safety measured by two items that were administered along with the PSPS scale in the same sample of this analysis. These two items came from a previously validated survey to assess patients' perception about safety in the ED, and was developed to be used in conjunction with ED satisfaction surveys. [58] The first item measured the overall level of patient safety by asking patients, 'Please rate the overall level of patient safety (defined as "freedom from any medical error or mistake) you felt during your acute stay' and responses were recorded on a 5-point likert scale (poor, fair, good, very good, and excellent) with higher scores indicating greater perceptions of overall level of patient safety. The second item measured specific safety concerns by asking patients, 'During your acute visit, were you ever concerned that any of the following would occur: falling and being injured, a mistake or error with medications, problems with medical equipment, a mistake by nurses, a mistake by physicians, being mistaken for another patient, wrong test/procedure, and would be misdiagnosed' and responses were coded as 'yes' or 'no'. The reports of concerns were converted to a summary variable, which was the total number of concerns per patient with a possible range from 0 to 8. [58]

To characterize our sample, socio demographics included: age (in years), sex (male or female), whether a patient graduated high school (yes or no), employed (yes

or no), on disability (yes or no), insured by Medicaid (yes or no), had a low annual income < $20,000 (yes, no, or did not mention), married or with significant other (yes or no), and lived alone (yes or no). Medical information included: whether a patient had SCA (sickle cell anemia) (yes or no), had chronic pain (yes or no), had any of the following complications (kidney disease, leg ulcer, stroke, retinopathy, avascular necrosis, priapism in males) (yes or no), on chronic transfusions (yes or no), on hydroxyurea in SCA only (yes or no), and pain level on arrival to the ED or IC using the pain intensity numeric rating scale (0-10). Healthcare use and access included: acute care utilization in the past year before study enrollment (number of acute care visits to the ED and IC), use of opioids (long acting only, short acting only, both, none), and whether a patient has a primary care provider (yes or no),

Statistical Analysis

Descriptive Statistics

We described the overall sample using frequencies and percentages, mean and standard deviation (SD), or median and interquartile range (IQR) when data were skewed. For each survey item, we calculated the mean and SD, median and IQR, skewness, kurtosis, and corrected item-total correlation (item-rest correlation). We examined the responses of each survey item for any floor or ceiling effects.

Both the mean and median (50^{th} percentile) measure the center of the data. The SD measures the variability and spread in the data around the mean and the IQR, which is the difference between the 75^{th} and 25^{th} percentile, measures the variability in the data around the median. Skewness and kurtosis are commonly used to examine the shape of the data distribution. Skewness is the degree of asymmetrical distribution around the mean while kurtosis is a measure of the tail shape relative to the overall shape of the distribution. For normally distributed data, skewness is close to zero and

kurtosis is three. [59] The corrected item-total correlation is the Pearson's correlation coefficient between each survey item score and the total survey score omitting the survey item that was assessed. A value of > 0.20 was considered satisfactory. [60]

Exploratory Factor Analysis

To be able to understand and interpret the concept of patient satisfaction with pain management based on the 15-item PSPS, we conducted an exploratory factor analysis (EFA). EFA is commonly used to evaluate the dimensionality of a concept (unobserved latent variable), which is a form of internal construct validity, and to reduce the number of survey items (measureable or observed variable) used to measure the specific concept. [61] Thus, we can infer the extent of patient satisfaction with pain management from the scores of the observed variables. We explored the relationships among the survey items using Pearson's correlation coefficient before proceeding to EFA since EFA mainly depends on the correlations among the survey items to explain the factor structure underlying these items.

Factor analysis is a three-step process: (i) selecting the number of factors, (ii) extracting the initial factors, and (iii) interpreting factor loadings. [62] To select the number of factors, we used principal component analysis (PCA), scree plots, and parallel analysis. When conducting PCA, we retained components that had eigenvalues > 1 based on the Kaiser Criterion. [63] Eigenvalues are interpreted as the sum of the correlation between each item and the component obtained; with 15 items, we will have 15 eigenvalues that will add up to 15. In other words, an eigenvalue represents the amount of the total variance over all the items that are attributable to the component. [64] After PCA, scree plots were used to graph the eigenvalues against the number of components. Scree plots are used along with PCA because PCA may overestimate the number of factors selected. [45] The number of factors selected

depends on the number of data points above the elbow, which is the break point in the data. [45] We then performed parallel analysis, which is a data simulation approach and is considered the gold standard in choosing the number of factors. After conducting PCA on each of the 100 simulated datasets with the same sample size, number of survey items, and same mean and variances of our survey items, we assumed that any correlation that exists is purely by chance. We then plotted the mean of each eigenvalue across the 100 datasets, thus expected from random data, and compared it with the real data. We would want components with eigenvalues greater than what we would get by chance.

We extracted the initial factors using maximum likelihood (ml). ML is the most common and frequent method used for factor extraction and is used with continuous indicators, which approximates our ordinal level response scale. One the main assumptions of ml is that our survey data must satisfy the multivariate normality assumption. [62] We tested the multivariate normality assumption of our items by examining kurtosis and skewness of each survey item (Kurtosis < 7 and skewness -2 to +2). [65] As a sensitivity analysis, we also used a least squares method (iterative principal factor) to extract the initial factors and compared it to the ml estimation method we mainly used. We considered dropping items with low factor loadings ($<$ 0.40) or with high uniqueness ($>$ 0.50) unless there was a strong conceptual reason for keeping those items. A factor loading is a measure of how much the survey item contributes to the factor. We considered a factor loading that is equal to or above 0.40 to be significant and statistically meaningful. We interpreted factor loadings as correlation coefficients between a survey item and a factor. Uniqueness is the proportion of the variance in a survey item that is not explained by the factor, which is similar to the residual variance.

Construct Validity

After conducting EFA, we calculated the mean score of the 15-item PSPS. We investigated the construct validity of the 15-item PSPS by testing the correlation between each of two validated safety measures and the PSPS mean score. We hypothesized that patients' perception of global safety in the acute care setting was positively correlated with patients' mean score of the PSPS, and that patients' number of perceived concerns was inversely correlated with patients' mean score of the PSPS. Our hypotheses were based on an extensive review of the literature linking patient satisfaction or outcomes related to satisfaction such as patient experiences with safety measures including reports by patients or objective measures. [66-72] Significance level was 0.05 for hypothesis testing.

Internal consistency

We calculated Cronbach's alpha (Range: 0-1) to determine the internal consistency reliability of the 15-item PSPS. Internal consistency is the extent of which the 15 survey items hang together as a measure of the concept of patient satisfaction. A value of > 0.70 was considered acceptable. [73]

Handling Missing Data

In our study, missing data was either due to unit non-response or item non-response. The unit response rate was calculated by dividing the number of patients who had complete responses to the survey by the number of eligible patients (patient who had first time visits). We decided to use complete case analysis since only $< 10\%$ of participants had item non-response; thus, this low proportion of missing items would likely not affect the validity of our results. [74] All analyses were performed using Stata/SE version 15.1 statistical software package (StataCorp LP, College Station, TX). [75]

2.4 Results

Descriptive Statistics

We enrolled 483 patients in the ESCAPED study and followed them for 18 months or until they were lost to follow-up. We excluded 115 patients who did not have VOC visits during their observation period. Of the 368 patients with visits, 212 patients responded to the survey. We excluded 5 (2.4%) patients who had some missing responses to the survey items, resulting in a final sample of 207 patients (207/368=56%). (Figure 2.2) Minimal data (<5%) was missing on some patient characteristics.

Table 2.1 shows the patient characteristics of the overall sample. The mean age of the sample was 33.8 years (SD, 10.8 years; range, 19 – 79 years), 63% were female, 82% graduated high school, and 37% were employed. The majority of patients were on Medicaid (56%) and about half of them had low annual income < $20,000 US dollars. About 66% of patients had SCA (hemoglobin-SS, Hgb-SS), which is the most severe type of SCD, with about 60% of patients with SCA on hydroxyurea at the start of the study. About two-thirds of patients had chronic pain and all patients in our sample were on opioids except for four patients. Less than 40% of patients had a comorbidity of kidney disease, leg ulcer, stroke, retinopathy, avascular necrosis, or priapism in males. The median pain level on arrival to the ED or IC was severe at 9 (IQR, 8-10; range: 0-10), and the median number of acute care visits in the past year was 5 per patient (IQR, 2-12; range: 0-65).

Table 2.2 represents the mean, SD, median, IQR, skewness, kurtosis, and corrected item-total correlation for each survey item. There was minimal negative skewness (Range: -0.2 to -1.2) and minimal positive kurtosis (range: 2.4 to 5.1). The

corrected item-total correlation was at least 0.65 and there were no floor or ceiling effects >30% based on the response distribution of each survey item. (Table 2.3)

Exploratory Factor Analysis

Factor analysis was conducted on the15-item PSPS scale. Correlations among the 15 items of the PSPS are reported in Table 2.4. Based on the correlations between the survey items, our data was appropriate for EFA.

(i) Selecting the Number of Factors

From PCA, there was one eigenvalue > 1 (EV = 10.21). With 10.21 of the 15 survey items being explained, the first component explained 68.1% of the total variance in the set of items. In the scree plot, the elbow, which is the point at which the angle of the line changes, was at the second component suggesting one component above the elbow. (Figure 2.3) From the parallel analysis, there was one component with an eigenvalue greater than the dotted line, which is the means of the eigenvalues from 100 simulated datasets. (Figure 2.4) Based on these results, we chose to retain one factor.

(ii) Extracting the Initial Factors and (iii) Interpreting Factor Loadings

Based on the kurtosis and skewness of the 15 items, our data satisfies the multivariate normality assumption. Therefore, we used a ml approach for our EFA. Table 2.5 presents the factor loadings and uniqueness values of the 15-item factor analysis using ml. All factor loadings ranged between 0.64 and 0.90 and were statistically significant. All uniqueness values were < 0.50 except for one item 'You received treatment in a timely manner', which had a uniqueness of 0.59. We decided

to keep this item since timeliness of care is a salient component of patient satisfaction with pain management.

As a sensitivity analysis, we used a least squared method (iterative principal factor) to estimate the factor loadings where the multivariate normality assumption does not have to be met. Our results using iterative principal factor estimation yielded similar results to the ml estimation method. (Table 2.6)

Construct Validity and Internal Consistency

The mean score of the 15-item PSPS was 5.4 (SD, 1.2) with a possible range from 1 to 7. As hypothesized, the mean PSPS score was positively correlated with patients' perception of overall level of patient safety (Spearman's rho = 0.63; $p < 0.001$). The mean PSPS score was inversely correlated with the number of concerns patients felt during their stay (r = -0.47; $p < 0.001$). The internal consistency reliability of the PSPS was high (Cronbach's $\alpha = 0.97$).

2.5 Discussion

The PSPS is the first specific patient satisfaction with pain management scale developed for adults with SCD to be used after the treatment of an acute VOC in the acute care setting. Our study provides preliminary evidence of the validity and reliability of the PSPS. Face and content validity was established by the ESCAPED research team. Factor analysis results show that a single factor represents 15 survey items demonstrating internal construct validity. Our scale shows evidence of external construct validity assessed by the correlation of the PSPS and two measures of patients' perception of safety, and has high internal consistency reliability.

Scales that have been developed in adults with SCD focused on patient-reported measures such as quality of care, quality of life, and self-efficacy. [54, 76-78] A systematic review to identify patient-reported outcome instruments in SCD found only one study to be related to patient satisfaction. [79] This study included the Adult Sickle Cell Quality of Life Measurement Information System Quality of Care (ASCQ-ME QOC) instrument to assess the quality of care in adults with SCD, who had an acute VOC and sought emergency care, and included treatment experiences in the ED as a subscale of quality of care. [54] However, we argue that the concept of patient satisfaction with pain management is different than the concept of patient experience and quality of care.

Unlike other multi-dimensional patient satisfaction questionnaires, our scale was unidimensional. We argue that satisfaction with pain management, which is the main indication for patients with SCD seeking care at an ED or IC, [13] is a specific concept inclusive of several aspects of care that are interrelated and interconnected supporting the unidimensionality of our scale. The acute care setting is a unique setting for rapid pain management with several interactions occurring at the same time, which makes it difficult for patients to conceptualize the different dimensions we (clinicians and researchers) label and perceive as discrete concepts.

External construct validity was tested by bivariate correlations between the PSPS mean score and two validated measures of patients' perception of safety. Our findings supported that reported in the literature where patients' perception of the degree of safety was positively correlated with patient satisfaction and patient experience outcomes in hospitalized patients in the US. [72] Similarly, a study conducted in the UK found that patients' perception of safety measured by a validated survey that consisted of 44 items and 9 subscales was statistically significantly

positively correlated with patient experience measured by a single item 'How likely are you to recommend this ward to your friends and family if they needed similar care or treatment?' ($r = 0.69$; $P < 0.001$). [70] We refer to these studies because patient satisfaction and patient experience are interrelated. [80] However, patient satisfaction is different than patient experience in that it reflects the extent of agreement between a patient's expectation of ideal care and perception of care received [20, 21] rather than the occurrence of certain events or processes of care during a clinical encounter. [80] Patient experience is embedded in patient satisfaction with both of these concepts reflecting patient-centered care.

There are several strengths in the design of our scale, which improves the measurement of patient satisfaction with pain management specific to adults with SCD. First, our scale has been developed in a sample of adults with SCD with a specific diagnosis of an acute VOC. Second, our scale included questions related to specific aspects of pain management in adults with SCD such as stigma related to SCD unlike other standard satisfaction scales that focus on more general issues with care. Third, we selected our survey items from previously validated measures. We further revised the items iteratively to ensure representativeness of the issues of pain management with SCD and brevity of our scale. Fourth, measuring patient satisfaction with pain management in the acute care setting including the ED and IC rather than in hospitals is more specific to the treatment of acute VOC in adults with SCD. Finally, patients are contacted within 72 hours of their acute care visits to minimize recall bias. Specific to our analysis, we used several different approaches to determine the number of factors and to fit our factor model.

There are some limitations to this study. First, we used a nonrandom nonprobability convenience sample of participants to be included in the larger

ESCAPED study where participants had access to both ED and IC, which may not be representative of the general population of adults with SCD. Patients who actively and regularly seek care at an ED or IC may have different levels of satisfaction than those who do not. However, we only aim to generalize our results to adults with SCD who have access to these acute care settings. To increase representativeness of our sample, our sample was recruited from four diverse geographic regions and clinical settings in the US. Second, although several strategies were incorporated into the recruitment and follow-up phase in the ESCAPED study, the response rate could have been higher to minimize non-response. Third, our sample size could have been larger to increase confidence in our results and to avoid biased estimates. However, our sample seems to be sufficient enough based on published rules of thumb of sample size requirements for factor analysis. [45] Fourth, although we used a rigorous approach to select survey items to be included in the scale, we might have omitted survey items that are important to the concept of patient satisfaction with pain management.

Further evidence of reliability and validity should be estimated in other samples of adults with SCD and in subsequent visits as well. With further testing, the PSPS could be helpful for studying the impact of quality improvement interventions on patient satisfaction with pain management. Further studies should investigate the association of patient satisfaction with pain management with different structures, processes of care, and patient outcomes to be able to be able to demonstrate the clinical significance of this scale.

2.6 Conclusions

The PSPS, an instrument for assessing patient satisfaction with pain management in adults with SCD after the treatment of an acute VOC in the acute care

setting, demonstrates preliminary evidence of validity and reliability. The PSPS shows promise for use in quality improvement intervention studies in the acute care setting to achieve patient-centered care in adults with SCD. Further research is needed to assess sensitivity to change in a longitudinal analysis.

Table 2.1 Patient characteristics of the overall sample (N=207)

Patient characteristics (N=207)	
Age (years), mean (SD), (Range: 19-79)	33.8 (10.8)
Sex (%)	
Female	130 (62.8%)
Male	77 (37.2%)
Graduated high school (%)	
Yes	169 (81.6%)
No	32 (15.5%)
Employed (%)	
Yes	77 (37.2%)
No	129 (62.3%)
On Disability (%)	
Yes	136 (65.7%)
No	70 (33.8%)
Insured by Medicaid (%)	
Yes	116 (56.0%)
No	89 (43.0%)
Low annual income < $20,000 (%)	
Yes	97 (46.9%)
No	97 (46.9%)
Did not mention	13 (6.2%)
Married or with significant other (%)	
Yes	47 (22.7%)
No	159 (76.8%)
Live alone (%)	
Yes	56 (27.1%)
No	151 (72.9%)
SCA (%)	
Yes	137 (66.2%)
No	67 (32.4%)
Chronic pain (%)	
Yes	157 (75.8%)
No	50 (24.2%)
Kidney disease (%)	
Yes	28 (13.5%)
No	177 (85.5%)
Leg ulcer (%)	
Yes	9 (4.3%)
No	196 (94.7%)
Stroke (%)	
Yes	34 (16.4%)
No	171 (82.6%)
Retinopathy (%)	
Yes	45 (21.7%)
No	159 (76.8%)
Avascular necrosis (%)	
Yes	69 (33.3%)
No	136 (65.7%)
Priapism (males only) (%)	
Yes	31 (40.3%)
No	46 (59.7%)
On chronic transfusions (%)	
Yes	27 (13.0%)
No	178 (86.0%)
On hydroxyurea (SCA only) (%)	
Yes	83 (60.6%)

No	54 (39.4%)
Pain level on arrival, median (IQR), (Range: 0 – 10)	9 (8-10)
Number of acute care visits in the past year, median (IQR), (Range: 0 – 65)	5 (2-12)
Opioid use (%)	
Long- acting only	7 (3.4%)
Short-acting only	116 (56.0%)
Both	80 (38.7%)
No opioids	4 (1.9%)
Have primary care provider (%)	
Yes	153 (73.9%)
No	54 (26.1%)

Note: Some frequencies do not add up to the total sample due to missing data in the following variables: graduated high school, employed, disability, insured by Medicaid, married or with significant other, SCA, kidney disease, leg ulcer, stroke, retinopathy, avascular necrosis, on chronic transfusions, and number of acute care visits in the past year
Abbreviations: SD, standard deviation; IQR, interquartile range

Table 2.2 Description of the satisfaction survey items (N=207)

	Mean (SD)	Median (IQR)	Skewness	Kurtosis	Corrected item-total correlation
1) The staff adequately assessed your pain	5.6 (1.3)	6 (5-7)	-1.2	5.1	0.73
2) You received treatment in a timely manner	5.3 (1.6)	5 (5-6)	-1.0	3.6	0.65
3) The doctor seemed to know just what to do for my problem	5.4 (1.3)	5 (5-7)	-0.7	3.4	0.86
4) Your pain was adequately controlled	5.1 (1.4)	5 (5-6)	-0.6	2.9	0.78
5) The provider ensured that the patient had enough medication to manage pain at home	5.0 (1.5)	5 (4-6)	-0.6	2.8	0.74
6) You were satisfied with the communication with the nurses	5.6 (1.4)	6 (5-7)	-1.2	4.8	0.73
7) Your nurse believed your reports about your pain	5.6 (1.2)	6 (5-7)	-1.0	4.5	0.78
8) You were satisfied with the communication with the doctors	5.5 (1.4)	6 (5-7)	-1.0	4.1	0.84
9) Your doctor believed your reports about your pain	5.5 (1.4)	6 (5-7)	-1.1	4.5	0.81
10) The doctor seemed warm and friendly to me	5.6 (1.3)	6 (5-7)	-1.1	4.6	0.81
11) I really felt understood by my doctor	5.4 (1.5)	5 (5-7)	-1.1	4.2	0.86
12) This is a doctor I would trust with my life	5.2 (1.6)	5 (4-7)	-0.9	3.5	0.86
13) The doctor has relieved my worries about my illness	5.0 (1.5)	5 (4-6)	-0.6	2.9	0.82
14) During your visit, you were allowed to participate in decisions about your pain treatment as much as you wanted to	5.3 (1.4)	5 (5-6)	-0.8	3.4	0.79
15) Overall, you are satisfied with the quality of care you received	5.5 (1.4)	5 (5-6)	-0.9	3.6	0.86

Abbreviations: SD, standard deviation; IQR, interquartile range

Table 2.3 Response distribution for each survey item (%) (N=207)

	1	2	3	4	5	6	7
1) The staff adequately assessed your pain	1.5	1.9	4.4	1.9	37.2	28.0	25.1
2) You received treatment in a timely manner	2.9	5.8	6.8	1.5	34.3	24.2	24.6
3) The doctor seemed to know just what to do for my problem	1.0	1.9	6.8	8.2	38.7	17.9	25.6
4) Your pain was adequately controlled	1.5	2.9	14.0	5.3	39.6	16.4	20.3
5) The provider ensured that the patient had enough medication to manage pain at home	2.4	3.4	14.5	7.7	33.3	21.7	16.9
6) You were satisfied with the communication with the nurses	2.4	1.9	4.8	1.9	35.3	24.2	29.5
7) Your nurse believed your reports about your pain	1.0	1.9	2.4	6.8	34.8	25.1	28.0
8) You were satisfied with the communication with the doctors	1.5	3.4	3.9	5.8	34.8	21.3	29.5
9) Your doctor believed your reports about your pain	2.4	3.4	1.9	7.3	34.8	23.2	27.1
10) The doctor seemed warm and friendly to me	1.9	1.5	3.9	5.8	35.3	22.7	29.0
11) I really felt understood by my doctor	3.9	2.4	4.4	6.8	32.9	22.2	27.5
12) This is a doctor I would trust with my life	4.8	3.4	3.4	13.5	29.5	19.3	26.1
13) The doctor has relieved my worries about my illness	2.4	1.9	14.0	10.1	33.3	18.8	19.3
14) During your visit, you were allowed to participate in decisions about your pain treatment as much as you wanted to	1.5	2.4	9.2	5.3	36.2	20.8	24.6
15) Overall, you are satisfied with the quality of care you received	1.0	2.9	7.7	2.4	36.7	21.3	28.0

1 = Very strongly disagree
2 = Strongly disagree
3 = Disagree
4 = Uncertain
5 = Agree
6 = Strongly agree
7 = Very strongly agree

Table 2.4 Correlation coefficients among the 15-item Patient Satisfaction with Pain Management in Adults with SCD (PSPS)

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1	-														
2	0.59	-													
3	0.63	0.60	-												
4	0.59	0.62	0.68	-											
5	0.49	0.46	0.72	0.61	-										
6	0.69	0.60	0.59	0.60	0.45	-									
7	0.67	0.60	0.66	0.68	0.56	0.71	-								
8	0.60	0.47	0.77	0.61	0.64	0.62	0.65	-							
9	0.60	0.43	0.74	0.60	0.62	0.56	0.63	0.81	-						
10	0.59	0.46	0.73	0.62	0.68	0.57	0.58	0.71	0.75	-					
11	0.61	0.49	0.78	0.66	0.67	0.58	0.66	0.82	0.82	0.80	-				
12	0.60	0.57	0.77	0.66	0.68	0.61	0.64	0.75	0.76	0.75	0.82	-			
13	0.56	0.51	0.80	0.65	0.68	0.60	0.60	0.72	0.71	0.71	0.76	0.76	-		
14	0.56	0.52	0.67	0.71	0.66	0.60	0.67	0.67	0.65	0.67	0.67	0.71	0.66	-	
15	0.64	0.67	0.74	0.73	0.67	0.69	0.70	0.76	0.69	0.70	0.77	0.74	0.72	0.71	-

Table 2.5 Factor loading patterns for 15-item factor analyses using maximum likelihood

Item	Factor loadings	Uniqueness
1) The staff adequately assessed your pain	0.72	0.48
2) You received treatment in a timely manner	0.64	0.59
3) The doctor seemed to know just what to do for my problem	0.88	0.23
4) Your pain was adequately controlled	0.78	0.39
5) The provider ensured that the patient had enough medication to manage pain at home	0.76	0.42
6) You were satisfied with the communication with the nurses	0.72	0.48
7) Your nurse believed your reports about your pain	0.77	0.41
8) You were satisfied with the communication with the doctors	0.87	0.25
9) Your doctor believed your reports about your pain	0.85	0.28
10) The doctor seemed warm and friendly to me	0.83	0.30
11) I really felt understood by my doctor	0.90	0.19
12) This is a doctor I would trust with my life	0.88	0.23
13) The doctor has relieved my worries about my illness	0.85	0.28
14) During your visit, you were allowed to participate in decisions about your pain treatment as much as you wanted to.	0.80	0.36
15) Overall, you are satisfied with the quality of care you received	0.87	0.25

Table 2.6 Factor loading patterns for 15-item factor analyses using iterative principal factor

Item	Factor loadings	Uniqueness
1) The staff adequately assessed your pain	0.74	0.46
2) You received treatment in a timely manner	0.66	0.57
3) The doctor seemed to know just what to do for my problem	0.88	0.23
4) Your pain was adequately controlled	0.79	0.37
5) The provider ensured that the patient had enough medication to manage pain at home	0.76	0.43
6) You were satisfied with the communication with the nurses	0.74	0.45
7) Your nurse believed your reports about your pain	0.79	0.38
8) You were satisfied with the communication with the doctors	0.85	0.27
9) Your doctor believed your reports about your pain	0.83	0.31
10) The doctor seemed warm and friendly to me	0.83	0.32
11) I really felt understood by my doctor	0.88	0.22
12) This is a doctor I would trust with my life	0.87	0.24
13) The doctor has relieved my worries about my illness	0.84	0.30
14) During your visit, you were allowed to participate in decisions about your pain treatment as much as you wanted to.	0.81	0.35
15) Overall, you are satisfied with the quality of care you received	0.88	0.23

Figure 2.1 Draft of survey items that reflect patient satisfaction with pain management

1. The staff adequately assessed your pain
2. You received treatment in a timely manner
3. The staff adequately responded to your pain
4. You were satisfied with the communication with the nurses
5. Your nurse believed your reports about your pain
6. You were satisfied with the communication with the physicians
7. Your doctor believed your reports about your pain
8. The doctor told me all I wanted to know about my illness
9. The doctor seemed interested in me as a person
10. The doctor seemed warm and friendly to me
11. The doctor seemed to take my problems seriously
12. I really felt understood by my doctor
13. This is a doctor I would trust with my life
14. The doctor seemed to know what (s) he was doing
15. The doctor has relieved my worries about my illness
16. The doctor seemed to know just what to do for my problem
17. You are satisfied with the treatment you received for your pain
18. Overall, you are satisfied with the quality of care you received
19. During your visit you were allowed to participate in decisions about your pain treatment a much as you wanted to
20. Your pain was adequately controlled
21. You received enough medication/treatment to deal with your pain
22. The provider ensured that you had enough pain medication to manage your pain at home
23. Bringing someone with me when I am in the ED/IC helps improve the quality of care I receive

Figure 2.2 Patient flow diagram

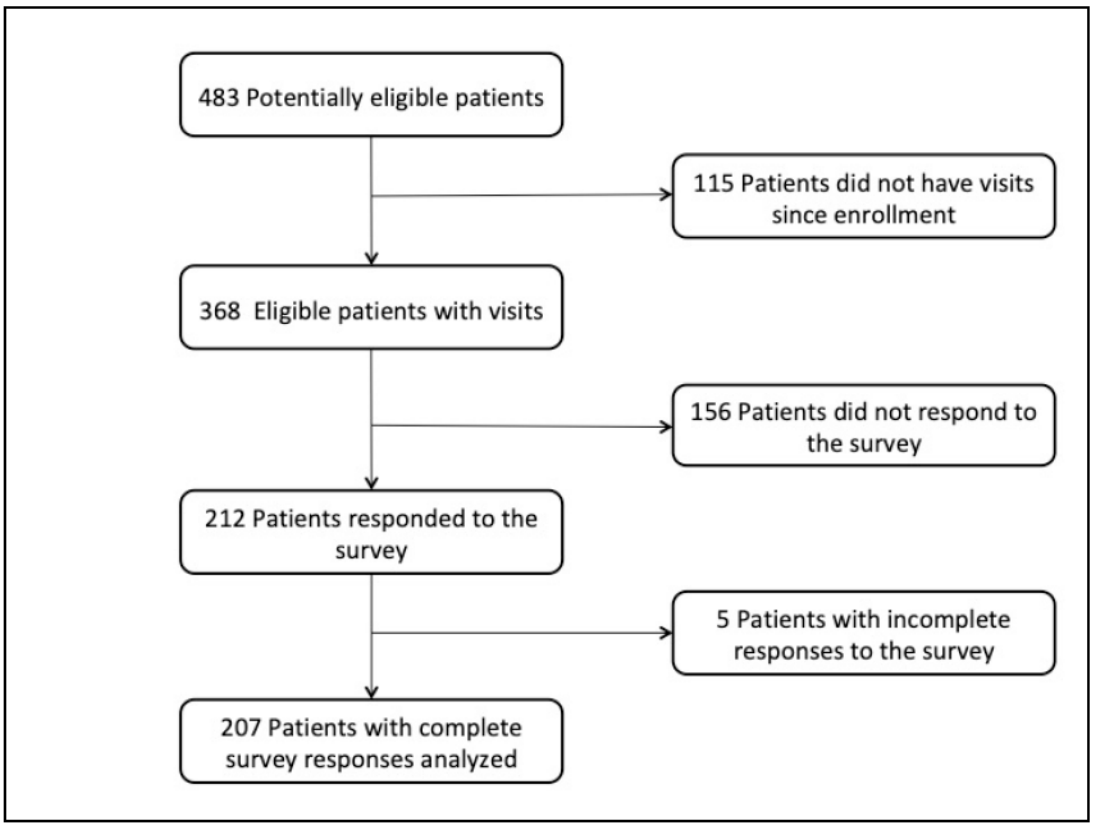


Figure 2.3 Scree plot

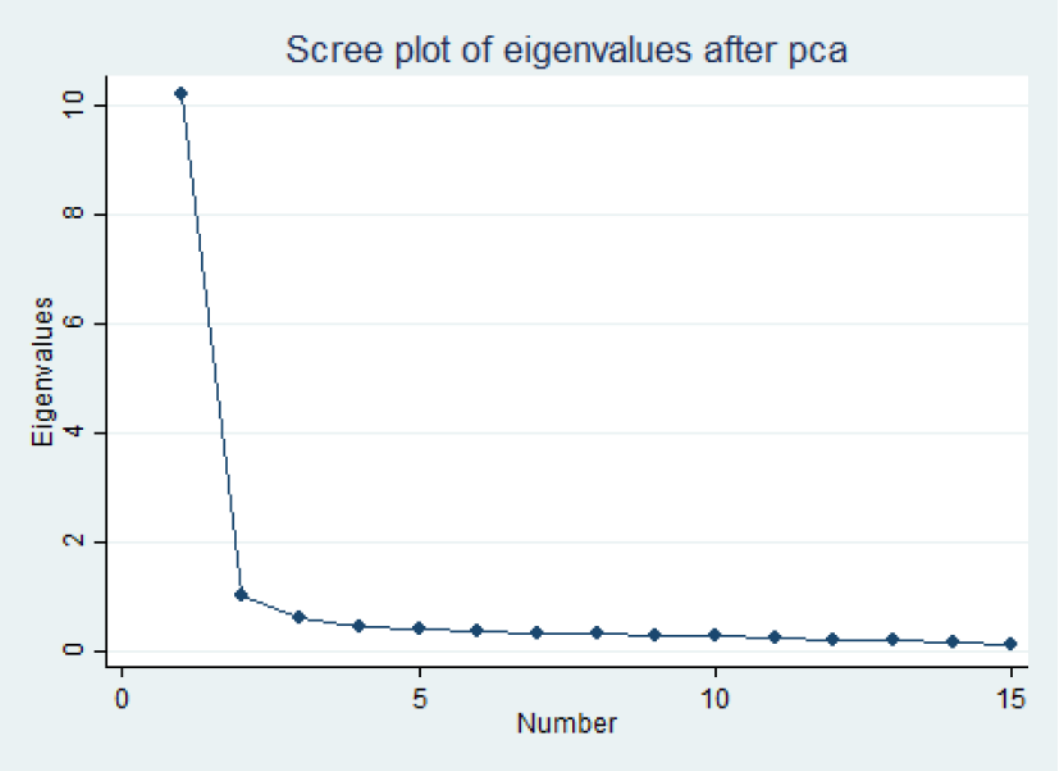
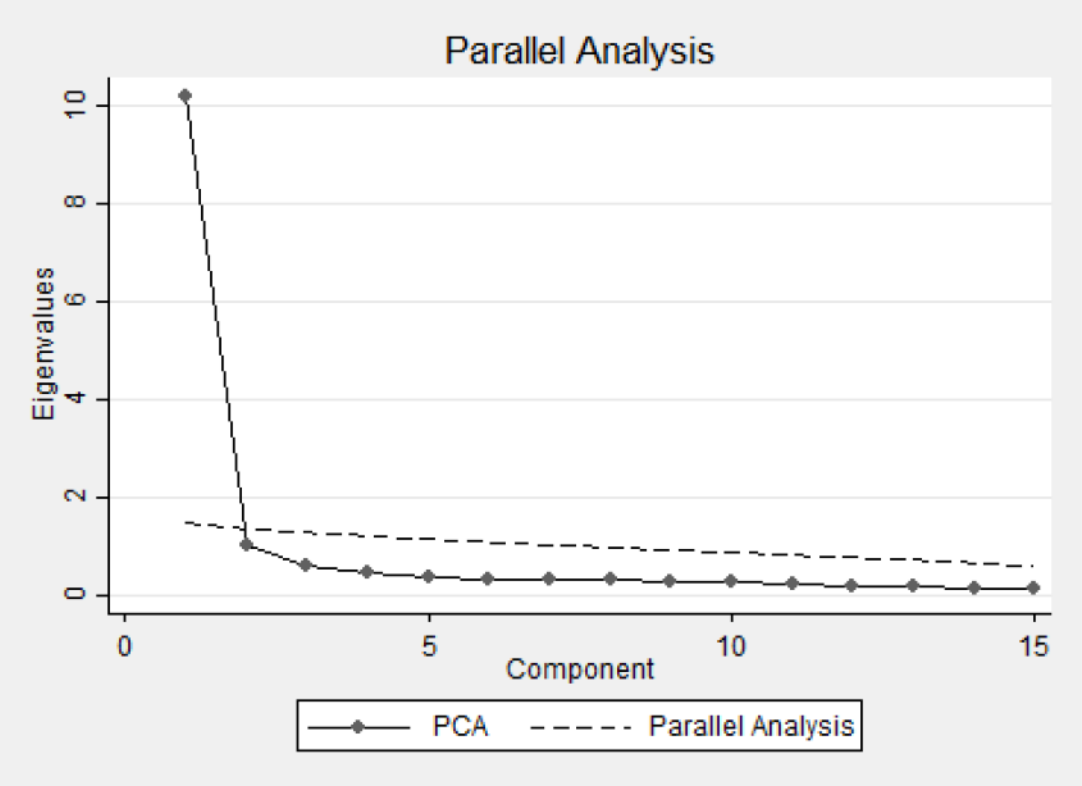


Figure 2.4 Parallel analysis



CHAPTER 3. PATIENT SATISFACTION WITH PAIN MANAGEMENT AFTER AN ACUTE VASO-OCCLUSIVE CRISIS IN EMERGENCY DEPARTMENTS AND SICKLE CELL INFUSION CENTERS

3.1 Abstract

Background: Patients with sickle cell disease (SCD) experience frequent vaso-occlusive crises (VOC), the leading cause of hospitalization and emergency department (ED) visits for these patients. Pain management in the ED has been suboptimal for adults with SCD. As an alternative to ED care, an infusion center (IC) is a comprehensive model of acute care delivery and may provide care that is more patient-centered. Patient satisfaction is an important measure for assessing the quality of care, specifically, patient-centered care. The objective of this study is to investigate the association between care provided in the ED or IC and adults' patient satisfaction with pain management for the treatment of acute VOC.

Methods: Our data was derived from a multisite prospective cohort study across four sites in four cities in the US. Our sample included adults (>18 years) with SCD living within 60 miles of a study site who had a first acute care visit since enrolled into the cohort and then responded to a satisfaction survey within 72 hours after their visit. Satisfaction with pain management was assessed using the newly validated scale: the **P**atient **S**atisfaction with **P**ain Management in **S**CD (PSPS). We used structural equation modeling to examine the association between the setting of care and adults patients' satisfaction with pain management, controlling for demographic and clinical characteristics.

Results: Our analytic sample included 207 adults who had complete responses to the PSPS: the response rate was 56%. On average, patients were 33.8 years old and 63% female. About 59% of our sample received care at an IC (n=122) and 41% received care at an ED (n=85). Our study shows that receiving care at an IC is statistically significantly associated with higher levels of satisfaction with pain management compared to receiving care at an ED (standardized $\beta = 0.40$, 95%CI: 0.29-0.51). This association remained positive and statistically significant even after controlling for age, sex, chronic pain, pain level on arrival, acute care utilization in the past year, and mode of survey administration (standardized $\beta = 0.35$, 95%CI: 0.23-0.47). Both models demonstrated adequate fit to the data.

Conclusions: Receiving care at an IC had a positive statistically significant association with patient satisfaction with pain management compared to receiving care at an ED in adults with SCD. The IC provides better pain management as evidenced by patients' responses to the PSPS scale. Increasing access to IC models of care can improve delivery of patient-centered care for treating acute VOC.

Keywords: Confirmatory factor analysis; emergency department; infusion center; pain management; patient-centered care; patient satisfaction; sickle cell disease; structural equation modeling

Running Title: Patient Satisfaction in Adults with SCD

3.2 Background

Sickle cell disease (SCD) is a group of inherited red blood cell disorders, which produces abnormal hemoglobin called hemoglobin S or sickle hemoglobin (HbS). [81] In the United States (US), it has been estimated that about 100,000 individuals live with SCD, which predominantly affects African Americans and Hispanics. [1] Adults living with SCD experience a life-long illness with a wide range of serious and severe forms of impairments, which reduces their life expectancy and impacts their quality of life. [5, 15] The most common diagnosis for emergency department (ED) visits for adults with SCD are acute vaso-occlusive crises (VOC), which is a severe form of frequent acute painful episodes that could be unmanageable and unpredictable. [2, 23] In 2006, about 74% of nationally estimated ED visits in adults with SCD were due to an acute VOC; however, pain management in the ED has been suboptimal for adults with SCD. [23]

Pain management for an acute VOC in the ED is often marked with long delays and inadequate management due to ED overcrowding and ED clinicians' lack of knowledge and expertise on how to manage these pain episodes. [24, 26] Patients have noted several issues with their pain management that are related to their interactions with their providers, such as negative provider attitudes, providers' lack of sympathy, perception of stigma and drug seeking behavior, and not sufficiently being involved in making care decisions. [24, 25] For those reasons, the ED may not be the optimal setting for this population.

As an alternative to ED care, an *infusion center* (IC) or a *day hospital* is an outpatient hospital-based facility that specializes in treating pain in adults with SCD, provides comprehensive services and continuity of care, and may provide care that is more patient-centered. Studies have shown that ICs provide timely pain management,

reduce hospital admissions, and increase patient satisfaction levels. [28-33] Patient satisfaction is an important measure for assessing the quality of care and reflective of patient-centered care. Patient-centered care is "providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions." [17] Patient satisfaction measures are an indication of patients' perception and expectation of their care, [82] which may be used to monitor healthcare performance and improve quality of care. [20] Only one study has compared patient satisfaction levels between the ED and IC in a single institution. Aisiku et al. found that patients who received care at a specialized center had higher mean satisfaction scores in global satisfaction, technical quality, accessibility and convenience, and financial aspects of care compared to care in the ED. No group differences were found in interpersonal manner, communication, or time spent with doctor. [28] Further research is needed to integrate the patient voice to evaluate outcomes that are meaningful to patients across different acute care settings and to be able to improve the quality of care for this population.

With a goal to achieve patient-centered care for adults with SCD, ICs might be a better place for providing care that is better quality relative to the ED. Our objective is to investigate the association between care provided in the ED or IC and adults' patient satisfaction with pain management for the treatment of acute VOC. We hypothesized that receiving care at an IC for the treatment of acute VOC is associated with higher levels of satisfaction with pain management compared to receiving care at an ED for adults with SCD.

3.3 Methods

Study Design and Study Setting

We used cross-sectional data of first time visits from April 2015 to December 2016 from the Examining Sickle Cell Acute Pain in the Emergency vs. Day Hospital (the ESCAPED) study. The ESCAPED study is a multisite longitudinal prospective cohort study to compare patient-centered outcomes between care in the ED and IC for the treatment of acute VOC across four US cities (Baltimore, Maryland; Cleveland, Ohio; Milwaukee, Wisconsin; and Baton Rouge, Louisiana). [83] Institutional review board was approved at all sites.

Study Population

Patients were recruited during regular outpatient clinic visits. Eligibility criteria included: age 18 years or older, diagnosis of SCD, live within 60 miles of the study site, and receive regular care at the study site. Exclusion criteria included: being well-controlled on chronic transfusions with no episodes of VOC in the past two years prior to enrollment, unable or unwilling to provide informed consent, and being pregnant. Patients who met these criteria were introduced to the study and then signed an informed consent and were asked to remain in the study for 18 months. A satisfaction survey was administered to patients in the ESCAPED study after each acute care visit for an uncomplicated VOC, which is an acute episode of pain with no other known cause that requires parenteral therapy for pain relief. [83] Of note, patients enrolled in the study may have visited an ED outside the four participating sites. While efforts were made to capture all visits, no information about the outside ED was obtained.

Data Collection

Survey instrument - The survey was administered to patients by trained research coordinators at each site within 72 hours after their acute care visit. Surveys were interview-administered by phone or self-administered to participants. When self-

administered, participants either completed the survey in-person before leaving the ED or IC using a paper-pencil or by computer where a link was sent via email. Different modalities were used and participants were compensated $25 for participation in the study to maximize response rates. [56, 57] Responses were then entered into the REDCap database from each site into one unified database. Patients' report of satisfaction with pain management after their first acute care visit was assessed using the **P**atient **S**atisfaction with **P**ain Management in **S**CD (PSPS) scale. The PSPS has been validated as part of the larger ESCAPED study using the same sample included in this analysis. The PSPS has demonstrated evidence of face, content, and construct validity with a high Cronbach's alpha ($\alpha = 0.97$). The PSPS included 15 items:

1. The staff adequately assessed your pain
2. You received treatment in a timely manner
3. The doctor seemed to know just what to do for my problem
4. Your pain was adequately controlled
5. The provider ensured that the patient had enough medication to manage pain at home
6. You were satisfied with the communication with the nurses
7. Your nurse believed your reports about your pain
8. You were satisfied with the communication with the doctors
9. Your doctor believed your reports about your pain
10. The doctor seemed warm and friendly to me
11. I really felt understood by my doctor
12. This is a doctor I would trust with my life
13. The doctor has relieved my worries about my illness

14. During your visit, you were allowed to participate in decisions about your pain treatment as much as you wanted to
15. Overall, you are satisfied with the quality of care you received

All 15 items had response options on a Likert scale from 1 to 7, where 1 was *very strongly disagree* and 7 was *very strongly agree*. These 15 items were used as indicators to represent the latent variable *patient satisfaction with pain management*, which was our dependent (endogenous) variable. An endogenous variable is affected or caused by one or more variables.

For descriptive purposes, two questions were included in the satisfaction survey on whether patients accessed care at an ED or IC with someone, and why they would bring someone to the ED or IC for their visit. Two open-ended questions were adopted from Bhakta's satisfaction survey 'What went well during your visit?' and 'What did not go well during your visit?' [50] These two open-ended questions were included as common practice in survey methodology, and to offer participants an opportunity to raise issues or concerns that were not included in the close-ended questions and to elaborate on their experiences during their acute care visit. [84]

Socio-demographic and clinical information – Socio-demographic and clinical information were self-reported by patients and collected from electronic medical records. A number of demographic and clinical variables were collected as part of the ESCAPED study but only a subset of these variables was included in this analysis.

1. The main independent (exogenous) variable was whether care was provided in the ED or IC. An exogenous variable predicts or causes one or more outcome.
2. Potential confounders were: age (in years), sex (male or female), daily chronic pain (yes or no), pain level on arrival to the ED or IC using the pain intensity numeric rating scale (0-10), acute care utilization (number of acute care visits

to the ED or IC in the past year before study enrollment), and mode of survey administration (self-administered or interviewer-administered). The selection of these potential confounders was based on the literature and expert opinion. [38, 56, 85] We theoretically hypothesized that each of these covariates is associated with receiving care in the ED or IC (main independent variable), associated with patient satisfaction (dependent variable), but not in the causal pathway between the main independent and dependent variables. [86]

3. Other socio-demographic covariates used to characterize our sample were: whether a patient graduated high school (yes or no), employed (yes or no), on disability (yes or no), insured by Medicaid (yes or no), had a low annual income < $20,000 (yes, no, or did not mention), married or with significant other (yes or no), and lived alone (yes or no).
4. Other clinical covariates used to characterize our sample were: whether a patient had sickle cell anemia (SCA) (yes or no), had any of the following complications in the past (kidney disease, leg ulcer, stroke, retinopathy, avascular necrosis, priapism in males) (yes or no), on chronic transfusions (yes or no), on hydroxyurea in SCA only (yes or no), use of opioids (long acting only, short acting only, both, none), and whether a patient has a primary care provider (PCP) (yes or no).

Conceptual Model

Our hypothesis was based on the Coyle and Battles' modified Donabedian's Structure – Process – Outcome (SPO) model for assessing quality of medical care. [35] The traditional Donabedian framework is made up of three components to measure the quality of medical care: structure, process, and outcome. Structure measures reflect the attributes of the clinical setting (e.g. facilities, equipment, and

staff to patient ratio). Process measures are informative on how care is being delivered and whether certain services of care are provided or not (e.g. communication between a patient and physician and physician prescribing an appropriate medication). Outcome measures are the effect or result of care on health status (e.g. improved patient satisfaction and reduced mortality). Donabedian suggests that these three components are interrelated; thus, structure may cause process and process may cause outcome. However, establishing this relationship may be complex and hard to demonstrate. [36] Coyle and Battles suggested incorporating pertinent antecedents of medical care into outcome assessment. Antecedents may include patient characteristics, such as genetics and socio-demographics, and health attitudes that may affect outcomes. [35] For this study, we focused on the association of structure (ED vs. IC) with outcome (patient satisfaction with pain management), incorporating pertinent antecedents of care that may influence this relationship. (Figure 3.1)

Statistical Analysis

We reported the socio-demographic and clinical characteristics of the overall sample and stratified by ED vs. IC to characterize our sample. For each survey item, we calculated the mean and standard deviation (SD) by ED vs. IC. We used structural equation modeling (SEM) to evaluate our hypothesis. SEM is a theory-driven statistical technique that allows researchers to test several models simultaneously including latent variables that are represented by a set of observed indicators. The SEM model consists of two components: the measurement model and the structural model. [64]

The measurement model, which is a confirmatory factor analysis (CFA) model, tests the relationship between a latent variable and the observed indicators (e.g.

survey items) that represent the concept being measured. The structural model is similar to a multiple regression model that tests the effect of an exogenous variable (or other predictors) on the latent (endogenous) variable. [87] In both models, relationships are estimated accounting for measurement error in the endogenous variable and observed indicators. Measurement error is a threat to internal validity and often referred to as the *error variance, error term, or unique variance*. When accounting for measurement error in the observed indicators, the measurement error in the latent variable is reduced, which allows for stronger predictive power and a more reliable measure of the endogenous variable. Since our data is mainly obtained from patient surveys, we assumed that our observed indicators are measured with some error. This assumption is in contrast to traditional regression techniques where we assume that there are no errors in the observed indicators. [64] Further, SEM uses the variance-covariance matrix of the input (sample) data to estimate the parameters and to reproduce the input variance-covariance matrix with a goal to minimize the difference between the estimated (predicted from our model) variance-covariance matrix and the observed (sample) variance-covariance matrix. [64]

Confirmatory Factor Analysis

CFA is a precursor for structural modeling and has the advantage of allowing each item to have its own unique variance in addition to the covariance (shared variance) of all 15 items that is explained by the latent variable. Being able to isolate the shared variance from the unique variance, which is noise to the data, will help obtain a better measurement of the latent variable. [64] To estimate parameters of our model, we first had to identify our CFA model using the following criteria:

1. Based on prior exploratory factor analysis (EFA), we imposed a one-factor model and we assumed that the error terms are normally distributed and not

correlated. We hypothesized that our measurement model is consistent with our data. [62]

2. Another important aspect of model identification is *statistical identification* or called the *T-Rule*, which is a necessary but not sufficient rule. Parameters in the model could not be estimated if the number of freely estimated parameters (unknown parameters) exceeds the number of pieces of information in the input variance-covariance matrix (known parameters). The difference between the known and unknown parameters is estimated and this difference is equivalent to the model's degrees of freedom (df). The model must be either *just-identified* (Difference = 0) or *over-identified* (Difference > 1). [62] In our CFA model, our model was over-identified (df = 90) with more known parameters (120 pieces of information in the input variance-covariance matrix) than freely estimated parameters (15 factor loadings, 15 unique variances). Having an over-identified model, allows us to use the df to assess goodness of fit of the model, which is how well the model reproduces the sample variance-covariance matrix using fewer numbers of freely estimated parameters. [62]
3. In a one-factor model, there has to be at least three indicators to represent the factor, which our CFA model satisfied. [62]
4. Since the unobserved latent factor has no defined unit of measurement, we fixed the variance of the factor to 1 to report the standardized coefficients. A standardized coefficient is interpreted as the correlation of the survey item with the latent factor. [62]

We performed CFA using maximum likelihood (ml) to assess our measurement model. ML is based on the principle of obtaining the estimated parameters that maximize the probability of observing the data if we were to collect this data from the

same population again. We examined key assumptions of using ml: 1) sufficient sample size, which was assessed based on the total number of participants and participant to survey item ratio; 2) observed indicators are measured on a Likert scale, which approximates the continuous scale; and 3) multivariate normality of the observed indicators, which we examined based on the skewness and kurtosis of each survey item. [45, 62, 65] For CFA results, we reported the standardized and unstandardized coefficients, 95% CI, and *p* values.

Structural Equation Modeling

After we have conducted CFA and assessed goodness of fit of the model, we specified two structural models to investigate the association between care provided in the ED or IC and adults' patient satisfaction with pain management for the treatment of acute VOC. Model 1 assessed the simple (unadjusted) association between ED vs. IC and patient satisfaction with pain management. Model 2 assessed the association between ED vs. IC and patient satisfaction with pain management controlling for age, sex, chronic pain, pain level on arrival, acute care utilization, and mode of survey administration. To prevent identification issues in our structural model, we checked whether the *null-B rule* and *recursive rule* were satisfied in our model. Both rules are sufficient but not necessary for identification of the SEM. The null-B rule requires that no endogenous variables can affect another. Our model only consists of one endogenous variable thus the null-B rule was satisfied. [88] The recursive rule requires that there is neither reciprocal causation nor correlated errors among endogenous variables, which our model satisfied. [89]

Parameter estimates were obtained using ml. To test how well our model fits the data, we used a number of goodness of fit tests in both the CFA model and structural model. To make sure our model is a good fit to our data, we used the root mean

squared error of approximation (RMSEA) and the standardized root mean squared residuals (SRMR), which are based on the fit of our predicted vs. observed covariance. To compare our model to an independence model, which is the smallest possible model comprising of variables with no relationships or correlations and only the variance of the variables are estimated, we estimated the comparative fit index (CFI), and the Tucker-Lewis index (TLI). General rules for acceptable fit have been suggested for RMSEA (< 0.08) with an upper bound of < 0.10 [90], SRMR (< 0.08), CFI (0.90 – 0.95), and TFI (0.90 – 0.95). We considered all four goodness of fit tests due to the imperfection of each test and the lack of a single superior test. Of note, goodness of fit tests should not be used exclusively to evaluate model fit. One should also evaluate the parameters in terms of size of the estimated parameter, directionality, and statistical significance. [62] For SEM results, we reported the standardized and unstandardized coefficients, 95% CI, and *p* values. For standardized estimates in SEM, we fixed the variance of the factor to 1. A standardized coefficient is interpreted as a standard deviation increase or decrease in the outcome in the IC compared to the ED. Significance level was 0.05.

Other Descriptive Questions

We reported frequencies and percentages in the overall sample and by care provided in the ED and IC in the two questions related to access to care. For open-ended questions, free-text responses were compiled and organized under themes based on what was consistently reported by patients. Themes emerged from the data but were also based on aspects of pain management that were presented in the close-ended survey questions. We provided verbatim quotes from patients to illustrate each theme. Although we considered the context of the ED and IC in our analysis, free-text

responses lacked richness and depth. Thus, no rigorous qualitative methods were used in the analysis of these two open-ended questions.

Non-Response and Handling Missing Data

We calculated the response rate using the number of patients who had complete responses to the survey divided by the number of eligible patients (patients who had first time visits). We used complete case analysis since < 10% of participants had some missing survey item responses. [74]

To assess the impact of non-response on the results of our study, we compared socio-demographic and clinical characteristics, and the setting of care (ED vs. IC) between respondents and non-respondents using descriptive statistics as appropriate to our data. Non-respondents were participants who had an acute care visit but did not respond to the survey or had some missing item responses. To adjust for non-response, we calculated non-response weights using available information about the non-respondents in the sample. We then assigned a weight for each respondent in the study by dividing the population percentage (participants who had an acute care visit) by the sample percentage (respondents to the survey).[91] We reran the two structural models using the weighted data and compared estimates to our results from the unweighted data. All analyses was done using Stata/SE version 15.1 statistical software package (StataCorp LP, College Station, TX). [75]

3.4 Results

Descriptive Statistics

Of the 483 adults with SCD who were enrolled in the ESCAPED study, 368 adults had an acute care visit. We excluded adults either due to complete non-response (n = 156) or item non-response (n = 5). Our analytic sample included a total

of 207 adults who had complete responses to the PSPS. (Figure 3.2) Response rate was 56% and < 5% of our data was missing on some patient or clinical characteristics. Overall, the survey was self-administered in 56% of the sample (n = 115) and was interviewer-administered in 44% of the sample (n = 92). On average, patients were aged 33.8 years with a range from 19 to 79 years and 63% were female. About 66% our sample had SCA genotype and about two-thirds reported chronic pain. The median pain level on arrival was nine and median number of acute care visits in the past year was five per patient.

About 59% of our sample received care at an IC (n=122) and 41% received care at an ED (n=85). For patients who received care at an IC, 64% of patients (78/122) completed the survey via self-administration whereas in the ED, 56% of (48/85) patients completed the survey via interviewer-administration, and this difference was statistically significant ($p = 0.004$). There were statistically significant differences ($p < 0.05$) between patients receiving care in the ED vs. IC with respect to age, pain level on arrival, married or with a significant other, and lived alone. Patients who received care at the IC were significantly older (35.8 vs. 31.0), had less pain level on arrival (8 vs. 9), were more likely to be married or with a significant other (30% vs. 12%), and less likely to live alone (21% vs. 35%) than patients who received care in the ED. Data describing patient characteristics are presented in Table 3.1.

For patients who received care at an IC, the overall mean satisfaction score was 5.8 (SD, 1.0) whereas for patients who received care at an ED, the overall mean satisfaction score was 4.8 (SD, 1.1). Table 3.2 presents the mean satisfaction scores by survey item in the ED and IC. See Figure 3.3 for graphical representation.

Confirmatory Factor Analysis

Our CFA consisted of one latent factor and 15 observed indicators. The results of the CFA indicated that the hypothesized measurement model is a good fit to our data with a RMSEA of 0.11 (90% CI: 0.09 - 0.12), SRMR of 0.04, a CFI of 0.93, and a TLI of 0.91. The standardized factor loadings of all 15 items were statistically significant ($p < 0.001$) and at 0.64 or above, which indicates that all observed variables were strongly correlated with the latent factor. (Table 3.3 and Figure 3.4)

Structural Equation Modeling

After evaluating the fit and factor loadings of the measurement model, we specified two structural models. In the first model, there was a positive association between care provided in the IC and patient satisfaction with pain management compared to care provided in the ED, and this association was statistically significant (standardized $\beta = 0.40$, 95%CI: 0.29-0.51; unstandardized $\beta = 0.74$, 95%CI: 0.49-0.99; $p < 0.001$). This model infers that receiving care at the IC is associated with a 0.40 SD increase in satisfaction compared to receiving care in the ED, and shows good fit to our data with a RMSEA of 0.11 (90% CI: 0.10 - 0.12), a SRMR of 0.05, a CFI of 0.91, and a TLI of 0.90 with 16.21% of the variance in the latent variable explained by this model.

In the second model, there was also a positive statistically significant association between care provided in the IC and patient satisfaction with pain management compared to the ED, controlling for age, sex, chronic pain, pain level on arrival, acute care utilization in the past year, and mode of survey administration (standardized $\beta = 0.35$, 95%CI: 0.23-0.47; unstandardized $\beta = 0.64$, 95%CI: 0.39-0.89; $p < 0.001$). For patients who received care in the IC, the probability of being satisfied increased by 35% of a SD compared to patients who received in the ED after controlling for certain socio-demographic and clinical characteristics. This model is a good fit to our data

with a RMSEA of 0.08 (90% CI: 0.07 - 0.09), SRMR of 0.05, a CFI of 0.90, and a TLI of 0.90 with 25.11% of the variance in the latent variable explained by the 2nd model.

Access to Care

Of the 207 patients in our sample, 124 patients (60%) came for care unaccompanied while 83 patients (40%) came for care with someone. No statistical difference was found across acute care settings. Of those who came to ED or IC with someone, there were different reasons for having a companion. The majority of patients (52%) could not get to the ED or IC without help due to their illness, 43% of patients reported that their companion keeps them company while they were being treated, 34% of patients could not get to the ED or IC due to transportation issues, 33% of patients reported that their companion helps make sure they get the treatment they need, and 22% of patients thought that their companion acts as their advocate while they are receiving care. There were no major differences between the groups of patients receiving care at the ED and IC.

Open-Ended Responses

Overall, 176/207 patients responded to the question 'What went well during your visit?' and 150/207 patients responded to the question 'What did not go well during your visit?' All responses were compiled to form four similar themes across both questions: 1) pain treatment and delivery, 2) staff communication and trust, 3) general or unspecified, and 4) issues not mentioned in the survey. Pain treatment and delivery included medication administration, timeliness of care, frequency and dose of medications delivered, and pain medication at home; staff communication and trust included how physicians, nurses, and physician assistants communicated with patients and how patients perceived their relationships with their providers; general or

unspecified were comments that were unspecific to a certain aspect of care; and issues not mentioned in the survey entailed environmental concerns or insurance issues. These themes applied to both patients receiving care at the ED or IC; there were no major differences in comments between both groups except for insurance issues that were specific to the IC. We present quotations for each theme in table 3.4.

Non-Response

When comparing characteristics between respondents and non-respondents in our sample, we found statistically significant differences ($p < 0.05$) in the setting of care and acute care utilization in the past year. (Table 3.5) Based on this information, we could assume that our outcome was missing at random (MAR); the probability of being satisfied may depend on the setting of care. We chose the setting of care to generate probability weights since it is the main independent variable in our analysis; thus, it may highly skew results if not accounted for. No differences were found between unweighted and weighted standardized coefficients, 95% CI, or *p*-values in the two models using SEM. (Table 3.6)

3.5 Discussion

In a sample of adult patients with SCD, recruited from multiple sites, we found that there were statistically significant associations between the setting of care and patient satisfaction with pain management. Our study shows that receiving care at an IC is associated with higher levels of satisfaction with pain management compared to receiving care at an ED for the treatment of acute VOC in adults with SCD. This association remained positive and statistically significant even after controlling for age, sex, chronic pain, pain level on arrival, acute care utilization in the past year, and mode of survey administration.

Patients are key stakeholders in their care; thus, their input and voice is crucial when evaluating the quality of their pain management. Patient satisfaction may provide insights into the extent of agreement between a patient's expectation of ideal care and perception of care received, and is closely related to patient-centeredness and quality of care [20, 21, 92] Based on patients' satisfaction with pain management, our results support the use of the IC over the ED for treating acute VOC in adults with SCD. In a study by Aisiku et al., authors used the Patient Satisfaction Questionnaire 18 (PSQ-18) to assess differences in patient satisfaction with care between patients who received care in the ED vs. IC. [28] Although conclusions were similar to our study, discrepancies between results may be due to the use of different measurement scales and use of different statistical techniques. We used the unidimensional PSPS scale that was developed in adults with SCD for the purpose of assessing patient satisfaction with pain management in the acute care setting instead of a generic satisfaction scale. We also might have differed in how we defined the concept of patient satisfaction; patient satisfaction with pain management is more specific than patient satisfaction with care, which is multidimensional. Our statistical techniques were more rigorous by modeling the latent variable and different associations using SEM rather than treating the outcome as an observed continuous variable. Further, our study represents adults with SCD with access to an ED and IC in multiple institutions across the US rather than a single institution, and patients' responses were referenced to a recent acute care visit as opposed to no reference to a specific visit.

There are several reasons that could explain the advantages of an IC in providing high quality care. For adults with SCD, ICs are equipped with trained and expert core staff that are knowledgeable and experienced in managing acute VOC. Staff is readily available for reassessment of pain and adjustment of dose, which may

be impeded in an ED due to staff high turnover and ED overcrowding. ICs provide continuity of care where patients are seen by hematologists and staff they know and may also return the following day for further treatment. [30, 93] However, access to and availability of IC remains an issue for adults with SCD.

Currently, there is a paucity of ICs for adults with SCD in the US that are located primarily in urban areas and are less likely to be networked nationwide. [12] Although SCD is more common in prevalence than hemophilia or cystic fibrosis in the US, more comprehensive centers for hemophilia and cystic fibrosis exist. Even where ICs exist for SCD, the majority of patients with SCD do not have access to these facilities. [94] The American Society of Hematology along with other organizations have identified access to care as one of the challenges in providing quality of care for patients with SCD. [95] Therefore, this study is timely in providing evidence that promotes the use of ICs over EDs as perceived by patients as a way to improve quality of care for this population.

There are limitations to our study. First, it is important to note that our study is restricted to adults who experienced an uncomplicated VOC. Adults who experience complicated VOC have to be evaluated and treated in the ED. Our study is also restricted to only those who have access to an ED and IC; thus, caution should be taken when generalizing results to other adults with SCD. Second, using a convenience sample may have introduced selection bias; patients who actively seek care at an IC may be different than patients who seek care at an ED. However, we tried to adjust for these differences in our analysis. Participants who chose to participate in the study may have been different than those who did not participate. Third, as in any survey study, there is a risk of non-response bias, which we adjusted for using probability weights. Study investigators have incorporated several strategies

in the design of the larger ESCAPED study to maximize response rates: use of different modalities to administer the survey, multiple contacts, reminders at each monthly phone call, and incentives. [91] Finally, based on our conceptual model, there could have been other models that further explain the relationship between the setting of care and patient satisfaction with pain management. We did not include any mediator variables (e.g. adherence to recommended guidelines for pain management, patient having an empathetic interaction with the provider, etc.) in our analysis due to the need for a larger sample size, the complexity of establishing a process-outcome relationship, and availability of data. [96] There could have been other confounders that are not known or measured at the time of patient care. We also did not look at differences between study sites nor did we use methods to account for clustered data because of the low enrollment in some sites and few numbers of clusters. Therefore, we cannot definitively infer a causal relationship.

Our study has several strengths. Our findings are an important contribution to the literature of quality of care in adults with SCD. Understanding the link between different acute care settings and patient satisfaction proposes system-level interventions to help achieve patient-centered care for adults with SCD. Our research was guided by a well-known conceptual framework – the Donabedian framework – that has been used for decades in assessing and improving the quality of care in different clinical settings. For this study, our aim was to represent adults with SCD who have access to ED and IC facilities; thus, patients were recruited from multiple sites from different locations in the US increasing representativeness of our sample. For our methodological approach, we used SEM, which is an innovative and rigorous statistical approach, to test our hypothesis.

Our study has implications for improving the quality of care, specifically, patient-centered care in adults with SCD. Although causal inference is limited in this study, our results may be used as evidence to promote expansion of ICs in other geographic areas, improve access to these ICs, and improve the quality of care in the ED. Further studies are needed to further explain the effect of receiving care at an IC vs. ED on patient satisfaction including mediator models and multi-level analyses to help target issues for quality improvement.

3.6 Conclusions

Receiving care at an IC had a positive statistically significant association with patient satisfaction with pain management compared to receiving care at an ED in adults with SCD. The IC provides better pain management as evidenced by patients' responses to the PSPS scale. Increasing access to IC models of care can improve delivery of patient-centered care for treating acute VOC.

Table 3.1 Patient characteristics of the overall sample and stratified by ED and IC (N=207)

Patient characteristic	ED (n = 85)	IC (n = 122)	Total sample (N = 207)
Age (yrs), mean (SD)* (Range: 19-79)	31.0 (8.7)	35.8 (11.7)	33.8 (10.8)
Sex (%)			
Female	54 (64%)	76 (62%)	130 (62.8%)
Male	31 (36%)	46 (38%)	77 (37.2%)
Graduated high school (%)			
Yes	68 (80%)	101 (83%)	169 (81.6%)
No	16 (19%)	16 (13%)	32 (15.5%)
Employed (%)			
Yes	31 (36%)	46 (38%)	77 (37.2%)
No	53 (62%)	76 (62%)	129 (62.3%)
On Disability (%)			
Yes	58 (68%)	78 (64%)	136 (65.7%)
No	26 (31%)	44 (36%)	70 (33.8%)
Insured by Medicaid (%)			
Yes	51 (60%)	65 (53%)	116 (56.0%)
No	33 (39%)	56 (46%)	89 (43.0%)
Low annual income <			
$20,000 (%)	43 (51%)	54 (44%)	97 (46.9%)
Yes	38 (45%)	59 (48%)	97 (46.9%)
No	4 (4%)	9 (8%)	13 (6.2%)
Did not mention			
Married or with significant			
other (%)*	10 (12%)	37 (30%)	47 (22.7%)
Yes	75 (88%)	84 (69%)	159 (76.8%)
No			
Live alone (%)*			
Yes	30 (35%)	26 (21%)	56 (27.1%)
No	55 (65%)	96 (79%)	151 (72.9%)
SCA (%)			
Yes	57 (67%)	80 (66%)	137 (66.2%)
No	26 (31%)	41 (34%)	67 (32.4%)
Chronic pain (%)			
Yes	64 (75%)	93 (76%)	157 (75.8%)
No	21 (25%)	29 (24%)	50 (24.2%)
Kidney disease (%)			
Yes	7 (8%)	21 (17%)	28 (13.5%)
No	77 (91%)	100 (82%)	177 (85.5%)
Leg ulcer (%)			
Yes	1 (1%)	8 (7%)	9 (4.3%)
No	83 (98%)	113 (93%)	196 (94.7%)
Stroke (%)			
Yes	19 (22%)	15 (12%)	34 (16.4%)
No	65 (76%)	106 (87%)	171 (82.6%)
Retinopathy (%)			
Yes	17 (20%)	28 (23%)	45 (21.7%)
No	67 (79%)	92 (75%)	159 (76.8%)
Avascular necrosis (%)			
Yes	24 (28%)	45 (37%)	69 (33.3%)
No	60 (71%)	76 (62%)	136 (65.7%)
Priapism (males only) (%)			
Yes	13 (42%)	18 (39%)	31 (40.3%)
No	18 (58%)	28 (61%)	46 (59.7%)
On chronic transfusions (%)			

Yes	9 (11%)	18 (15%)	27 (13.0%)
No	75 (88%)	103 (84%)	178 (86.0%)
On hydroxyurea (SCA only) (%)			
Yes	31 (54%)	52 (65%)	83 (60.6%)
No	26 (46%)	28 (35%)	54 (39.4%)
Pain level on arrival, median (IQR) (Range: 0 – 10)*	9 (8-10)	8 (8-9)	9 (8-10)
Number of acute care visits in the past year, median (IQR) (Range: 0 – 65)	5 (2-11)	5 (2-12)	5 (2-12)
Opioid use (%)			
Long- acting only	2 (2%)	5 (4%)	7 (3.4%)
Short-acting only	53 (62%)	63 (52%)	116 (56.0%)
Both	28 (33%)	52 (43%)	80 (38.7%)
No opioids	2 (2%)	2 (1%)	4 (1.9%)
Have a primary care provider (%)			
Yes	57 (67%)	96 (79%)	153 (73.9%)
No	28 (33%)	26 (21%)	54 (26.1%)

* $p < 0.05$ between care in the ED and IC

Note: Some frequencies do not add up to the total sample due to missing data in the following variables: graduated high school, employed, disability, insured by Medicaid, married or with significant other, SCA, kidney disease, leg ulcer, stroke, retinopathy, avascular necrosis, on chronic transfusions, and number of acute care visits in the past year

Abbreviations: ED, emergency department; IC, infusion center; SD, standard deviation; IQR, interquartile range

Table 3.2 Mean scores of each survey item by care provided in the ED and infusion center IC (N=207)

	ED (n=85)		IC (n=122)	
	Mean	**SD**	**Mean**	**SD**
1) The staff adequately assessed your pain	5.1	1.2	5.9	1.2
2) You received treatment in a timely manner	4.5	1.7	5.9	1.2
3) The doctor seemed to know just what to do for my problem	4.9	1.2	5.7	1.3
4) Your pain was adequately controlled	4.4	1.5	5.6	1.2
5) The provider ensured that the patient had enough medication to manage pain at home	4.3	1.5	5.4	1.3
6) You were satisfied with the communication with the nurses	5.0	1.4	5.9	1.3
7) Your nurse believed your reports about your pain	5.1	1.3	6.0	1.0
8) You were satisfied with the communication with the doctors	5.0	1.3	5.9	1.3
9) Your doctor believed your reports about your pain	5.1	1.5	5.7	1.3
10) The doctor seemed warm and friendly to me	5.1	1.4	5.9	1.2
11) I really felt understood by my doctor	4.8	1.6	5.8	1.3
12) This is a doctor I would trust with my life	4.5	1.7	5.7	1.3
13) The doctor has relieved my worries about my illness	4.6	1.5	5.4	1.4
14) During your visit, you were allowed to participate in decisions about your pain treatment as much as you wanted to	4.8	1.5	5.7	1.2
15) Overall, you are satisfied with the quality of care you received	4.8	1.4	6.0	1.1

Abbreviations: ED, emergency department; IC, infusion center; SD, standard deviation

Table 3.3 Standardized and unstandardized coefficients for confirmatory factor analysis (CFA)

Item	Standardized coefficient (95%CI)	Unstandardized coefficient (95%CI)
1) The staff adequately assessed your pain	0.72 (0.65-0.79)*	1.00 (fixed)
2) You received treatment in a timely manner	0.64 (0.56-0.72)*	1.11 (0.87-1.34)*
3) The doctor seemed to know just what to do for my problem	0.88 (0.85-0.91)*	1.29 (1.09-1.48)*
4) Your pain was adequately controlled	0.78 (0.72-0.83)*	1.24 (1.03-1.46)*
5) The provider ensured that the patient had enough medication to manage pain at home	0.76 (0.71-0.82)*	1.27 (1.04-1.49)*
6) You were satisfied with the communication with the nurses	0.72 (0.65-0.79)*	1.10 (0.89-1.30)*
7) Your nurse believed your reports about your pain	0.77 (0.71-0.83)*	1.05 (0.87-1.23)*
8) You were satisfied with the communication with the doctors	0.87 (0.83-0.90)*	1.32 (1.11-1.52)*
9) Your doctor believed your reports about your pain	0.85 (0.81-0.89)*	1.31 (1.10-1.52)*
10) The doctor seemed warm and friendly to me	0.83 (0.79-0.88)*	1.22 (1.02-1.41)*
11) I really felt understood by my doctor	0.90 (0.87-0.93)*	1.49 (1.27-1.72)*
12) This is a doctor I would trust with my life	0.88 (0.85-0.91)*	1.55 (1.31-1.79)*
13) The doctor has relieved my worries about my illness	0.85 (0.81-0.89)*	1.39 (1.16-1.61)*
14) During your visit, you were allowed to participate in decisions about your pain treatment as much as you wanted to.	0.80 (0.75-0.85)*	1.23 (1.02-1.44)*
15) Overall, you are satisfied with the quality of care you received	0.87 (0.83-0.90)*	1.31 (1.11-1.52)*

* $p < 0.001$; statistically significant

Table 3.4 Themes and quotations of responses to open-ended questions

What went well?	Theme	Quotation
	Pain treatment and delivery	"The amount of medication and frequency it was delivered" "I was seen and treated for my pain in a timely manner" "They got my IV on first stick"
	Staff communication and trust	"The nurses really took the time to talk and understand my problems and issues" "Communication with the ED physician"
	General or unspecified	"Everything went well" "Good experience"
	Issues not mentioned in the survey	"Linen change" "They had me in a room right next to the entrance and then moved me to a better room"
What did not go well?	**Theme**	**Quotation**
	Pain treatment and delivery	"The amount of time I had to wait to be treated" "Had to remind them to administer home meds" "Number of sticks for an IV"
	Staff communication and trust	"Doctor did not listen to my symptoms and opinions on what works best" "Staff did not believe reports about my pain and needing meds until I threw up"
	General or unspecified	"Everything went well" "Nothing to say"
	Issues not mentioned in the survey	"Waiting area was too cold" "Problems with insurance"

Abbreviations: IV, intravenous; ED, emergency department

Table 3.5 Comparison between respondents and non-respondents (N=368)

	All eligible participants (N = 368)	Respondents (n = 207)	Non-respondents (n = 161)	*P* - value
Setting of care (%)				
ED	188 (51%)	85 (41%)	102 (64%)	<0.001
IC	179 (49%)	122 (59%)	58 (36%)	
Missing 1				
Age (years), mean (SD), (Range: 19-79)	33.9 (10.7)	33.8 (10.8)	34.0 (10.7)	0.908
Missing 1				
Sex (%)				
Female	224 (61%)	130 (63%)	94 (59%)	0.430
Male	143 (39%)	77 (37%)	66 (41%)	
Missing 1				
Graduated high school (%)				
Yes	294 (80%)	169 (82%)	125 (78%)	0.471
No	61 (17%)	32 (15%)	29 (18%)	
Missing 13				
Employed				
Yes	133 (36%)	77 (37%)	56 (35%)	0.738
No	230 (63%)	129 (62%)	101 (63%)	
Missing 5				
On Disability (%)				
Yes	246 (67%)	136 (66%)	110 (69%)	0.467
No	118 (32%)	70 (34%)	48 (30%)	
Missing 4				
Insured by Medicaid (%)				
Yes	204 (56%)	116 (56%)	88 (55%)	0.365
No	150 (41%)	86 (42%)	64 (40%)	
Missing 14				
Low annual income < $20,000 (%)	179 (49%)	97 (47%)	82 (51%)	0.506
Yes	168 (46%)	97 (47%)	71 (44%)	
No	20 (5%)	13 (6%)	7 (4%)	
Did not mention				
Missing 1				
Married or with significant other (%)	78 (21%)	47 (23%)	31 (19%)	0.443
Yes	287 (78%)	159 (77%)	128 (80%)	
No				
Missing 3				
Live alone (%)				
Yes	103 (28%)	56 (27%)	47 (29%)	0.623
No	264 (72%)	151 (73%)	113 (71%)	
Missing 1				
SCA (%)				
Yes	253 (69%)	137 (66%)	116 (73%)	0.075
No	104 (28%)	67 (32%)	37 (23%)	
Missing 11				
Chronic pain (%)				
Yes	264 (72%)	157 (76%)	107 (67%)	0.058
No	103 (28%)	50 (24%)	53 (33%)	
Missing 1				
Pain level on arrival, median (IQR) (Range: 0 – 10)	9 (8 – 10)	9 (8 -10)	9 (8 -10)	0.361

Missing 46				
Number of acute care visits in the past year, median (IQR) (Range: 0 – 90) Missing 8	4 (2 -11)	5 (2 – 12)	4 (1 – 9)	0.014

Abbreviations: ED, emergency department; IC, infusion center; SD, standard deviation; IQR, interquartile range; SCA, sickle cell anemia

Table 3.6 Unweighted and weighted results of two models using structural equation modeling (SEM)

	Unweighted		Weighted	
	Standardized coefficients	**95% CI**	**Standardized coefficients**	**95% CI**
Model 1. Unadjusted				
IC vs. ED	0.40*	0.29 - 0.51	0.40*	0.29 – 0.52
Model 2. Adjusted+				
IC vs. ED	0.35*	0.23 - 0.47	0.35*	0.24 – 0.47

+Adjusted for age, sex, chronic pain, pain level at arrival, acute care utilization in the past year, and mode of survey administration

* $p < 0.001$; statistically significant

Figure 3.1 Conceptual model of the relationship between ED vs. IC and patient satisfaction with pain management

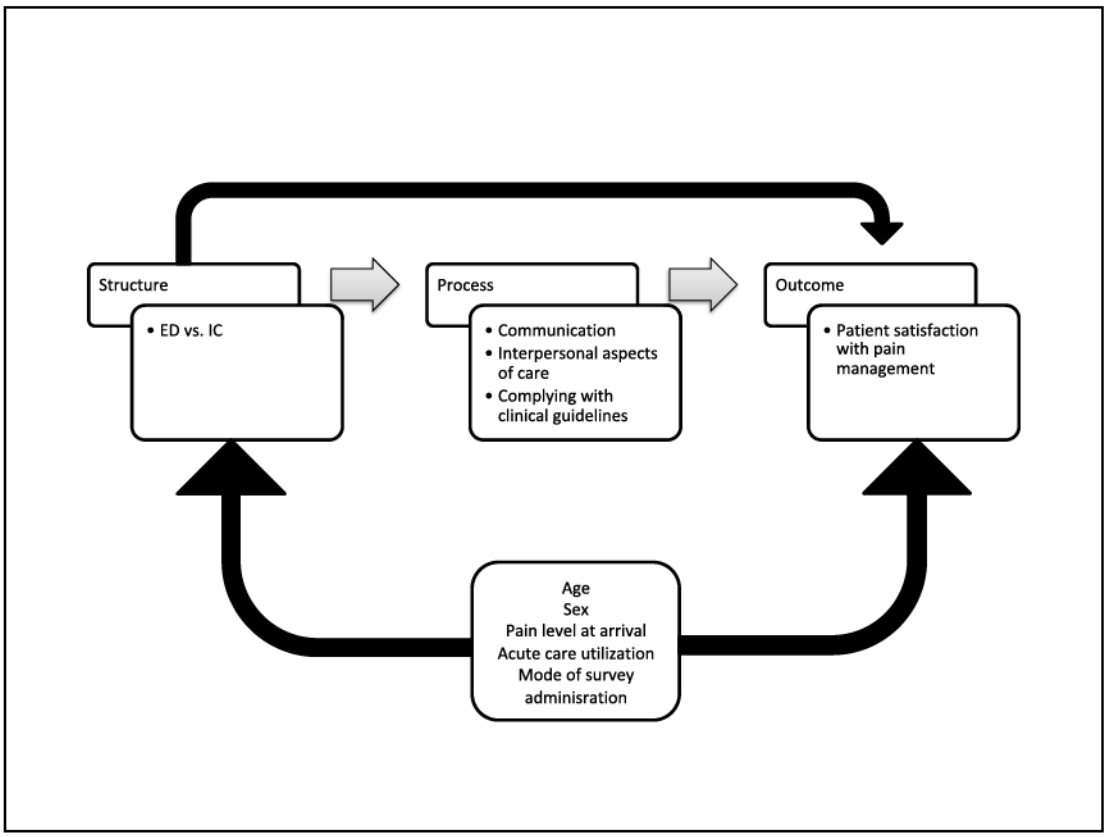


Figure 3.2 Patient flow diagram

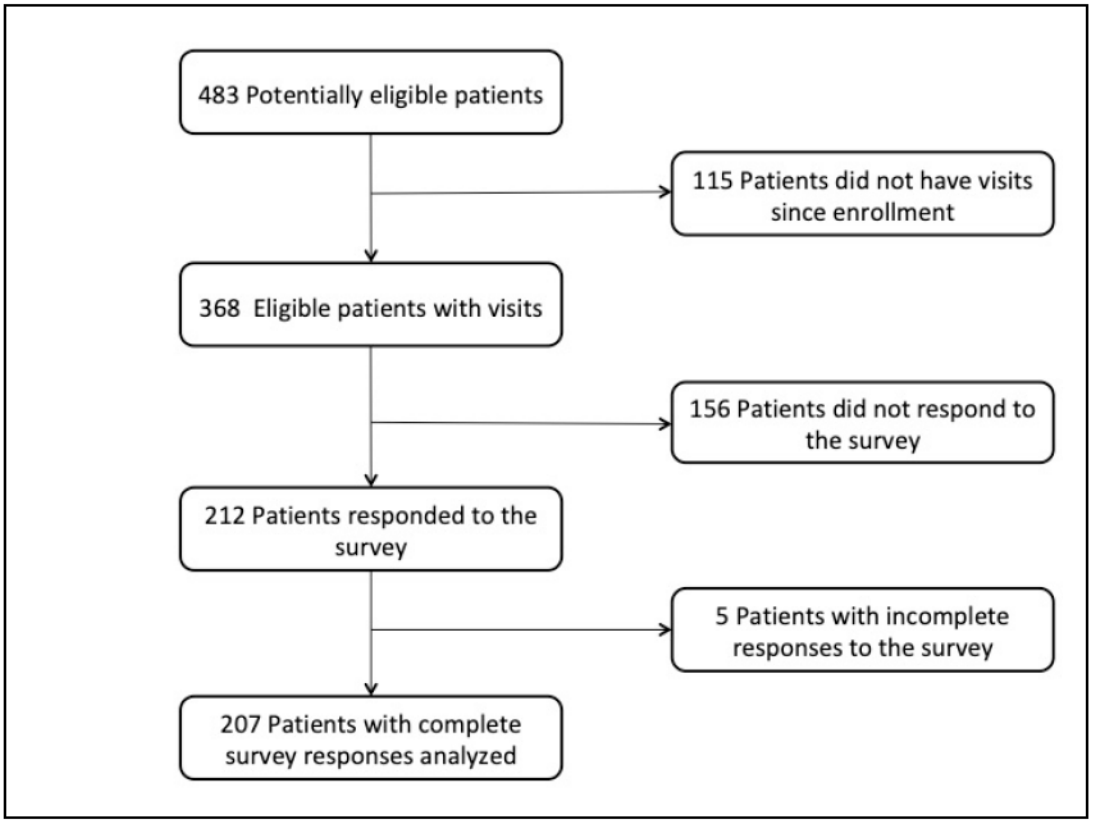
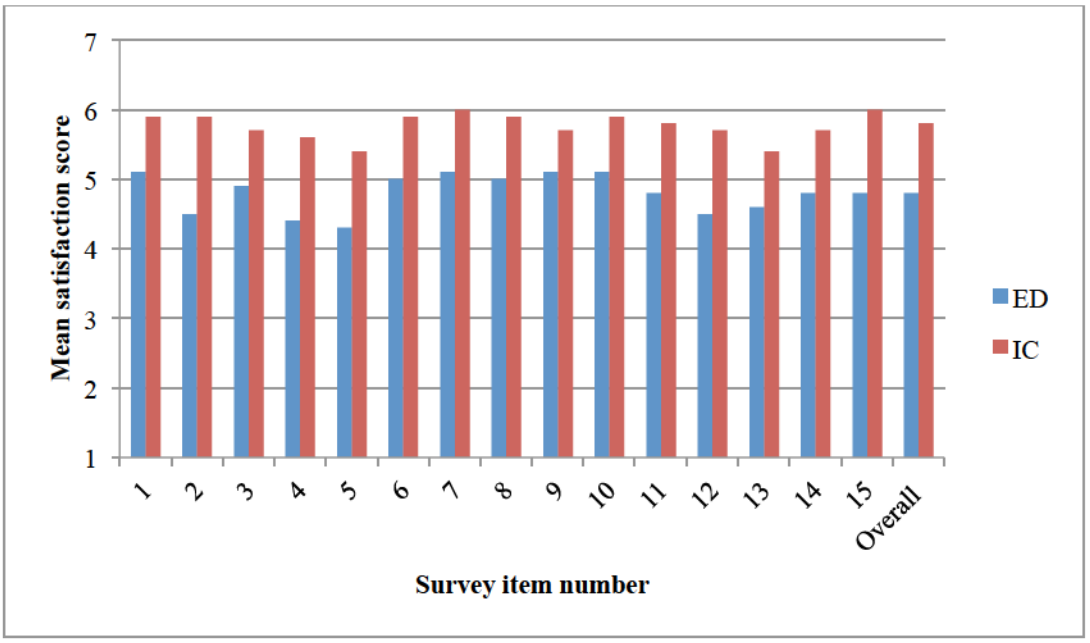
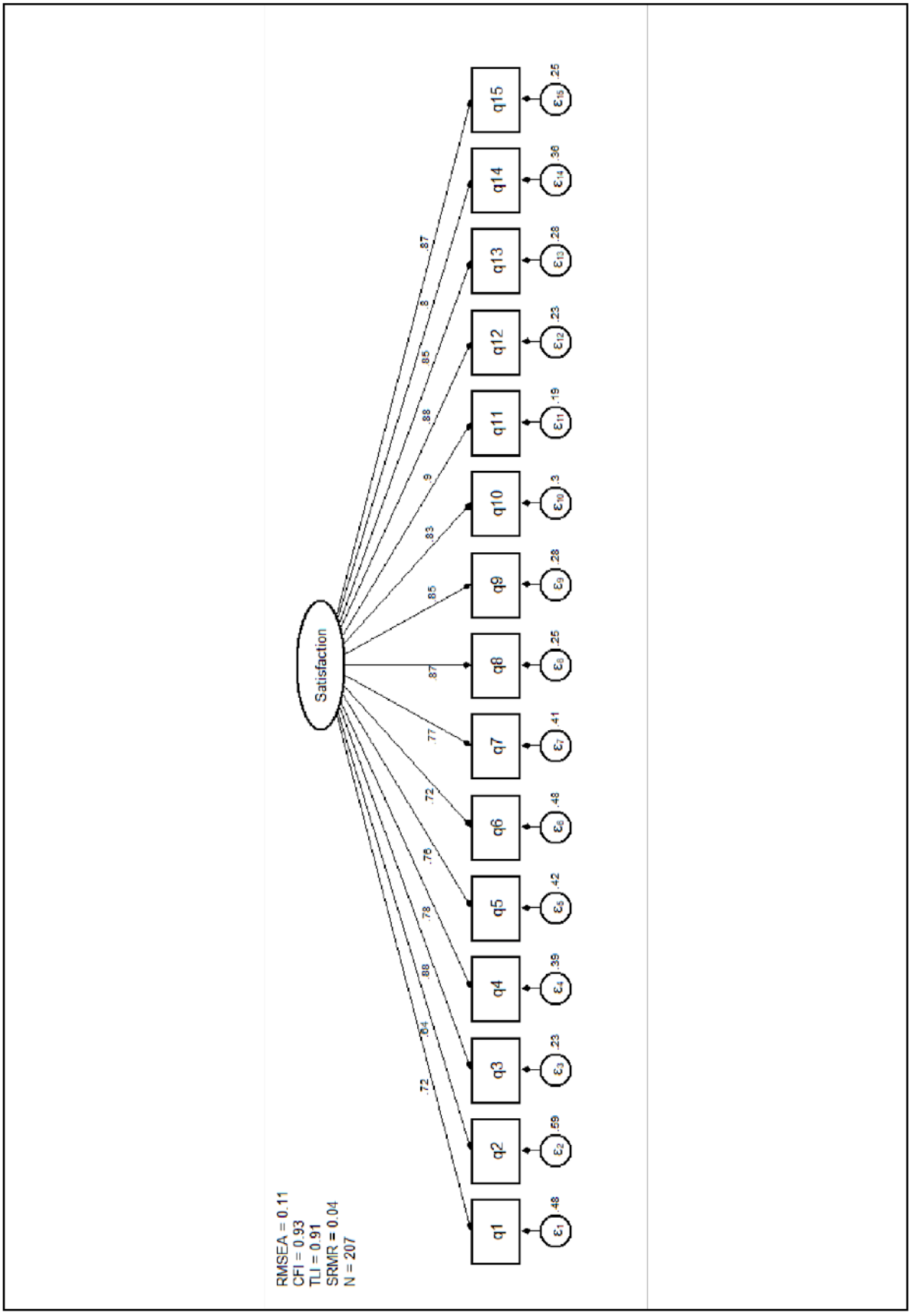


Figure 3.3 Mean satisfaction scores in the ED and IC by survey item



Note: Overall score was calculated by adding responses of all 15 questions and then dividing them by 15

Figure 3.4 Confirmatory factor analysis (CFA) model of the Patient Satisfaction with Pain Management in Adults with SCD (PSPS) scale (N=207)



CHAPTER 4. PERCEPTIONS OF SAFETY IN ADULT PATIENTS WITH SICKLE CELL DISEASE IN EMERGENCY DEPARTMENTS AND SICKLE CELL INFUSION CENTERS

4.1 Abstract

Background: Adults with sickle cell disease (SCD) frequently experience acute painful vaso-occlusive crises (VOC), which is the most common indication for hospitalizations and emergency department (ED) visits. However, the ED is a challenging place to provide optimal care for adults with SCD and is prone to medical errors. Sickle cell infusion centers (IC) are alternative to ED care and provide care that is comprehensive with continuity of care. Patient safety has been raised by our patient partners as being concerning in the ED. However, patients' perception of safety in the acute care setting among adults with SCD has not been investigated. The goal of this study is to examine the association between the setting of care (ED or IC) and patients' perception of safety during an acute care visit for the treatment of an acute VOC among adults with SCD.

Methods: We conducted a cross-sectional analysis of first time visits to the ED and IC for acute VOC, as part of a multisite prospective cohort study across four sites in the US. Participants completed a safety survey within 72 hours after the visit. Patients were asked to rate their overall level of patient safety on a 5-point likert scale (poor, fair, good, very good, and excellent), which was dichotomized into greater perceptions of safety (excellent or very good) vs. lower perceptions of safety (good, fair, or poor). Patients were also asked to report the presence or absence of eight specific safety concerns. Each specific safety concern was modeled as a binary outcome. We also calculated the number of perceived specific concerns per patient.

We fit logistic regression and negative binomial regression models for our outcomes as a function of setting of care, controlling for socio-demographics, pain severity, acute care utilization, and mode of survey administration when appropriate.

Results: Of 368 patients who had first time visits, 205 (56%) responded to the survey: 87 (42%) received care at an ED and 118 (58%) received care at an IC. Patients who received care at an IC were significantly older (35.3 vs. 31.2) and had worse pain level on arrival (9 vs. 8) than patients who received care at an ED. Controlling for age, gender, pain level on arrival, and number of acute care visits in the past year, patients in the IC had 79% lower odds of lower perceptions of overall level of patient safety (OR, 0.21; 95%CI, 0.10-0.41; p <0.001), had 62% fewer numbers of specific concerns (IRR, 0.38; 95%CI, 0.20 – 0.73; p <0.01) relative to patients in the ED. Patients in the IC had 72% (OR, 0.28; 95%CI, 0.11-0.71) lower odds of perceiving a medication error, and had 87% (OR, 0.13; 95%CI, 0.04-0.41) lower odds of perceiving a mistake by a nurse as compared to patients in the ED. No statistical association was found between the setting of care and falling and being injured, problems with medical equipment, mistakes by physicians, being mistaken for another patient, wrong test/procedure, and misdiagnosis.

Conclusions: Our results demonstrate an association between the setting of care and patients' perception of overall level of patient safety and number of perceived specific concerns. Medication errors and mistakes by nurses were the two specific safety concerns that were associated with the setting of care. Patients' perception of safety in adults with SCD could be incorporated in safety improvement initiatives to improve patient safety and overall patient experience. Adoption of the IC model may result in

improved perceptions of patient safety in adults with SCD. Further study is needed to better understand the key factors that may be contribute to patients' perception of safety.

Keywords: Emergency department; infusion center; medical error; patient engagement; patient involvement; patient perception; patient safety; safety concern; sickle cell disease

Running title: Perceptions of Safety in Adults with SCD

4.2 Background

Patient safety has been an emerging public health priority since the release of the first Institute of Medicine (IOM) report on patient safety *To Err Is Human: Building a Safer Health System*. The report concluded that medical errors are common, system-level factors contribute to medical errors, and improvements could be made to ensure patient safety. [97] While there has been some progress to improve patient safety, [98, 99] patient involvement in reporting safety issues and preventing medical errors or adverse events has not commonly been incorporated in safety improvement efforts. [100] Patients' experiences and perceptions about patient safety precede patient involvement in safety-related behaviors, and might be associated with important measures such as patient satisfaction. [34, 100]

Patients' perception of safety in the emergency department (ED) has been less studied compared to the hospital setting. The ED setting is prone to medical errors and adverse events for several reasons including overcrowding and patient volume, no continuity of care, treating a wide variety of illnesses, inexperienced staff, and staff shift changes. [101] In a systematic review of studies that took place in the US, Canada, and Australia, the prevalence of adverse events ranged from 0.6% to 6% in the ED. [102] The National Emergency Department Safety Study, conducted in 62 EDs in the US, found that the incident of adverse events was 4.1 adverse events per 100 patient visits and 37% of these adverse events were preventable medical errors. [103] Despite these numbers, the ED still remains a necessary setting for patients presenting with pain. [104]

Adults with SCD commonly experience acute painful vaso-occlusive crises (VOC) requiring rapid evaluation and pain management. [105] Although VOC are the most common indication for ED visits and hospital admissions, the ED is a

challenging place to provide optimal care for adults with SCD, which may compromise patient safety. [13, 105] As an alternative for ED care, sickle cell infusion centers (IC) are specialized outpatient hospital-based centers that provide comprehensive services and continuity of care. Studies have shown that ICs provide timely pain management, reduce hospital admissions, and increase patient satisfaction levels. [28-33] Recently, based on discussions with the Patient-Centered Outcomes Research Institute (PCORI) patient advisory counsel, the issue of safety has been raised as being concerning in the ED given the lack of provider experience and knowledge to manage patients with SCD. Yet, patient safety has not been investigated in adults with SCD neither have associations with the acute care setting ever been explored.

We propose that patients' perception of safety in adult patients with SCD might be associated with where they receive care for the treatment of an acute VOC. It is important to understand how people feel about their safety, which may contribute to their involvement in detecting and preventing medical errors. Although exploratory, this research could identify areas for quality and safety improvement initiatives. The overall goal of this study is to examine the association between the setting of care (ED or IC) and patients' perception of safety during an acute care visit for the treatment of an acute VOC among adults with SCD. The objectives of this study are:

1) To investigate the association between care provided in the ED or IC and perceived overall level of patient safety. We hypothesized that patients who receive care in the IC will have lower odds of perceiving lower levels of overall patient safety relative to patients who receive care in the ED.
2) To investigate the association between care provided in the ED or IC and perception of each of eight specific safety concerns; including falling and

being injured, medication errors, problems with medical equipment, mistakes by nurses, mistakes by physicians, being mistaken for another patient, wrong test/procedure, and misdiagnosis. We hypothesized that patients who receive care in the IC will have lower odds of perceiving each of eight specific safety concerns compared to patients who receive care in the ED.

3) To investigate the association between care provided in the ED or IC and number of perceived specific safety concerns. We hypothesized that patients who receive care in the IC will more likely report fewer numbers of perceived specific safety concerns compared to patient who receive care in the ED.

4.3 Methods

Study Population and Study Design

Participants in this study are from the ESCAPED (Examining Sickle Cell Acute Pain in the Emergency vs. Day Hospital) prospective cohort study of adults with SCD. In the ESCAPED study, patients were recruited from April 2015 to December 2016 across four sites in four cities in the US: Baltimore, Maryland; Cleveland, Ohio; Milwaukee, Wisconsin; and Baton Rouge, Louisiana. Each study site had a hospital-based IC and ED. Institutional review board was approved at all sites.

Participants were recruited from outpatient clinic visits and were eligible for enrollment if they met the following criteria: age of 18 years or older, had a confirmed diagnosis of SCD, lived within 60 miles of a study site, and received regular care at a study site. Participants were excluded if their SCD was well controlled on chronic transfusions with no episodes of acute VOC in the two years before enrollment, unable or unwilling to provide informed consent, or pregnant. At enrollment, participants provided informed consent for inclusion in the study and were followed up for 18 months until the end of the study or loss to follow-up. [83]

We conducted a cross-sectional analysis of first time acute care visits (defined as first visit after enrollment) in the ED and IC for adults enrolled in the ESCPAED study and who have completed a survey after their first visit. Surveys were either self-administered in-person or electronically (survey link was sent via email), or interviewer-administered by phone within 72 hours after the visit. All visits were for treatment of an uncomplicated VOC, which is an acute episode of pain with no other known cause that requires parenteral therapy for pain relief. [83] Information on patient and clinical characteristics were retrieved from electronic medical records and self-reported by patients.

Measurements

Dependent (outcome) variables. A survey that included questions about patient safety was administered along with a larger survey to assess patient satisfaction with pain management in the acute care setting for the treatment of an acute VOC. Survey items related to patient safety were adopted from a previously validated survey with no adjustments or changes from the ESCAPED research team. The safety survey was developed based on focus groups and individual interviews with patients to understand how they viewed patient safety and what specific safety concerns were important to them. After survey items were developed, further refinement of survey items was done using cognitive interviews and pilot testing in a sample of adults who were admitted to a hospital ED. [58]

To assess patients' perception of overall level of patient safety, patients were asked, "Please rate the overall level of patient safety (defined as freedom from any medical error or mistake) you felt during your acute stay" and responses were recorded on a 5-point likert scale (poor, fair, good, very good, and excellent). To assess patients' perception of specific safety concerns, patients were asked, "During

your acute visit, were you ever concerned that any of the following would occur: falling and being injured, a mistake or error with medications, problems with medical equipment, a mistake by nurses, a mistake by physicians, being mistaken for another patient, wrong test/procedure, and would be misdiagnosed" and responses for each specific concern were coded as yes or no. Patients' perception of specific safety concerns was modeled in two ways: 1) each specific concern was evaluated individually as a binary outcome, and 2) number of perceived specific concerns per patient was calculated with a possible range from 0 to 8.

Independent variable. The main independent variable was whether patients received care for the treatment of an acute VOC in the ED or IC.

Covariates. The selection of potential confounding variables was based on the safety literature in general practices and hospital settings. [106, 107] Socio-demographic covariates included sex (male or female) and age (in years). We considered pain level on arrival (0-10) to account for pain severity, and number of acute care visits in the past year including visits to the ED and IC cumulatively to account for acute care utilization. Mode of survey administration (self-administered or interviewer-administered) was also considered as a confounder since it might affect patients' responses. [56] To characterize our sample, in addition to the potential confounding variables, we used the following variables: graduated high school (yes or no), employed (yes or no), low annual income < $20,000 (yes, no, or did not mention), insured by Medicaid (yes or no), and sickle cell anemia (SCA) genotype (yes or no).

Statistical Analysis

Descriptive Statistics

We reported patient characteristics in the overall sample and stratified by our main independent variable (ED or IC). For characteristics that were measured on a

continuous scale, we reported mean and standard deviation (SD) and median and interquartile range (IQR). For categorical variables, we reported frequencies and percentages. We used descriptive statistics to explore differences between patients receiving care in the ED vs. IC across all patient characteristics. We used student two-sample *t*-test and Mann-Whitney U test, when data was skewed, for continuous variables. [108, 109] We used chi-squared test of independence and Fisher's exact test, when samples were small, for categorical variables. [108]

Patients' Perception of Overall Level of Patient Safety

The association between care provided in the ED or IC and patients' perception of overall level of patient safety was evaluated using multivariable logistic regression. We dichotomized this outcome as greater perceptions of safety (excellent or very good) vs. lower perceptions of safety (good, fair, or poor) to be able to employ logistic regression analysis. Community-based organization members from all study sites, who were involved in the ESCAPED study, helped determine the cutoff point suggesting that the standards of patient safety should be at least *very good* to qualify as greater perceptions of safety. While overall level of patient safety was originally measured as an ordinal outcome, we dichotomized this outcome to refrain from using ordinal logistic regression. Ordinal logistic regression requires the proportional odds assumption to be met, which is often violated and may lead to biased results. [110] Multicollinearity of potential confounders was evaluated using variance inflation factors (threshold 10). A number of models were employed using different combinations of our potential confounding variables. [111] We first assessed the fit of the model by testing the statistical significance of our covariates using the likelihood ratio test. The likelihood ratio test compares the fit of one model (null model) nested into another model (extended model) using the log likelihood. A statistically

significant likelihood ratio test (p <0.05) favors the extended model over the null model. To finalize our model, we assessed the overall goodness of fit of the model using Hosmer-Lemeshow test; a high p-value indicates that the observed outcome is not significantly different from the expected outcome (predicted by the model) and thus the model is a good fit to the data. [112, 113]

Patients' Perception of Specific Safety Concerns

The association between care provided in the ED or IC and patients' perception of specific safety concerns was assessed using logistic regression and negative binomial regression. We modeled each specific safety concern as a function of the setting of care using logistic regression. In these models, we did not adjust for any confounders due to the small number of reported specific concerns in this sample. [114] When modeling the outcome as number of perceived specific safety concerns per patient, we initially tested whether our outcome was over-dispersed. We found that the variance (1.56) was greater than the mean (0.55) of number of perceived specific concerns, which suggests over-dispersion. Thus, we used negative binomial regression, rather than Poisson regression, to test for associations between the setting of care and number of perceived specific safety concerns. [115] We presented four negative binomial models. The first model tested the unadjusted association between the setting of care and number of perceived specific concerns. In the second model, we adjusted for socio-demographics (age and gender) whereas in the third model, we adjusted for pain severity and acute care utilization in addition to socio-demographics. In the fourth model, we adjusted for socio-demographics, pain severity, healthcare utilization, and mode of survey administration. In all four models, we used the likelihood ratio test of alpha to detect whether our negative binomial model would

have yielded different results than the corresponding Poisson model. A statistically significant p-value (p <0.05) suggests that the Poisson model is not appropriate.

For logistic regression analysis, estimates of associations were presented as odds ratios (OR) along with 95% confidence intervals (CI) and p-values to test statistical significance. For negative binomial regression analysis, estimates of associations were presented as incidence rate ratios (IRR) and corresponding 95% CI and p-values to test statistical significance. All statistical tests assumed an alpha level of 0.05 and all tests were two-tailed.

Non-Response and Handling Missing Data

The response rate was calculated based on the number of participants who had complete survey responses divided by the number of patients with first time visits. We used complete case analysis since our sample had low item non-response (<5%). As a sensitivity analysis, we compared the distribution of our main independent variable and other covariates mentioned previously between respondents and non-respondents using descriptive statistics, as appropriate to our data. Participants who had either complete or item non-response were considered non-respondents. We calculated non-response weights based on the setting of care variable, which was available for non-respondents. We considered patients who had an acute care visit as our population and patients who had complete survey responses as our sample. We then divided the population proportion by the sample proportion. [91] We applied the weights to all descriptive tests and regression models, and compared estimates to our results from the unweighted data. Statistical analysis was performed using Stata/SE version 15.1 statistical software package (StataCorp LP, College Station, TX). [75]

4.4 Results

Patient Characteristics

Our analytic sample included 205 patients who had first time visits and who had complete responses to the outcomes under study. For an overview of the patient flow process see Figure 1. The response rate was 56% (205/368 = 56%) with 57% of patients responding to the self-administered survey and 43% of patients responding by telephone. Forty-two percent of patients (n=87) received care at an ED and 58% of patients (n=118) received care at an IC. The majority of patients in the ED responded by telephone interview (55%) whereas the majority of patients in the IC responded to the self-administered survey (66%), and this difference was statistically significant ($p < 0.01$).

Of the 205 patients, the majority of patients were female (63%), and the average age was 33.5 (SD, 10.6). With respect to socio-economic status, 82% of our sample were high school graduates, 62% were unemployed, and 48% reported low annual income. There were statistically significant differences ($p <0.01$) between patients receiving care in the ED vs. IC with respect to age and pain level on arrival. Patients who received care at the IC were significantly older (35.3 vs. 31.2) and had worse pain level on arrival (9 vs. 8) than patients who received care in the ED. However, clinically, the rating of pain of 8 and 9 are both categorized as *severe*. [116] Further characteristics can be seen in Table 1.

Patients' Perception of Overall Level of Patient Safety

In the overall sample, 31% of patients had lower perceptions of overall level of patient safety. For patients who received care in the ED vs. IC, 50% vs. 17% of patients had lower perceptions of overall level of patient safety during their visit ($p < 0.001$). (Table 2) In the unadjusted model, patients in the IC had 80% lower odds of lower perceptions of overall patient safety relative to patients in the ED (OR, 0.20; 95%CI, 0.11 – 0.38; $p <0.001$). In the adjusted multivariate model, controlling for

age, gender, pain level on arrival, and number of acute care visits in the past year, the odds of lower perceptions of overall level of patient safety for patients receiving care in the IC was 0.21 times (95%CI, 0.10 - 0.41; p <0.001) that of the odds for patients receiving care in the ED. We compared the adjusted model to the unadjusted model using the likelihood ratio test, which indicated that the inclusion of age, gender, pain level on arrival, and number of acute care visits in the past year contribute significantly to the modeled association ($p < 0.05$). The overall fit of our model was good based on the Hosmer-Lemeshow test (Chi-square test, 5.46; 8 degrees of freedom; p, 0.71). As a sensitivity analysis, we ran our regression models using a cutoff point of good, very good, or excellent to indicate greater perceptions of overall level of patient safety instead of very good or excellent. Results differed in magnitude but were similar in direction and statistical association. (See Appendix B)

Patients' Perception of Specific Safety Concerns

In the overall sample, 24% of patients perceived to have a specific safety concern during their acute care visit. In the ED, 38% of patients had a specific safety concern whereas in the IC only 14% of patients had a specific safety concern (p <0.001). The most common concerns reported were medication errors (n= 23; 11%) and mistakes by nurses (n= 22; 11%), which were statistically significantly different among patients in the ED vs. IC (p <0.05). With respect to medication errors, 18% vs. 6% of patients perceived a medication error in the ED and IC, respectively. With respect to mistakes by nurses, 21% vs. 3% of patients perceived a mistake by a nurse in the ED and IC, respectively. (Table 3)

With regards to specific safety concerns, the setting of care was statistically significantly associated with medication errors and mistakes by nurses. Patients in the IC had 72% lower odds of perceiving a medication error, and had 87% lower odds of

perceiving a mistake by nurse as compared to patients in the ED. These two associations were found to be statistically significant (p <0.01). However, there was no statistical association between the setting of care and falling and being injured, problems with medical equipment, mistakes by physicians, being mistaken for another patient, wrong test/procedure, and misdiagnosis. (Table 4)

Further, the association between the setting of care and number of perceived specific safety concerns was statistically significant across all models 1-4. (Table 5) In the unadjusted model (model 1), for patients receiving care at an IC, the expected number of specific concerns decreased by 64% (IRR, 0.36; 95%CI, 0.19 – 0.69; p < 0.01) compared to care at an ED. After adjusting for age and gender in model 2, patients who received care at an IC had a higher likelihood of fewer number of specific concerns by a factor of 0.38 (95%CI, 0.20 – 0.72; p < 0.01) compared to patients who received care at an ED. In model 3, the association remained significant after adjusting for age, gender, pain level on arrival, and acute care utilization (IRR, 0.38; 95%CI, 0.20 – 0.73; p <0.01). In model 4, we adjusted for mode of survey administration, age, gender, pain level on arrival, and acute care utilization and the association remained significant (IRR, 0.37; 95%CI, 0.19 – 0.72; p <0.01). In all four models, the likelihood ratio test of alpha was statistically significant (p <0.05) suggesting that the Poisson model was not appropriate.

As a sensitivity analysis, we also modeled the outcome of perception of specific safety concerns by dichotomizing the number of specific concerns per patient into perception of any specific safety concern vs. no perception of any specific safety concern. The setting of care was statistically significantly associated with the perception of any specific safety concern. Relative to patients in the ED, patients in the IC had 72% lower odds of perceiving any specific safety concern (OR, 0.28;

95%CI, 0.14 – 0.54; p <0.001). In the adjusted multivariate model, controlling for age, gender, pain level on arrival, and acute care utilization, the odds of perceiving any specific safety concern for patients receiving care in the IC was 0.30 times (95%CI: 0.15-0.61; p <0.01) that of the odds for patients receiving care in the ED. The overall fit of our model was good based on the Hosmer-Lemeshow test (Chi-square test, 7.25; 8 degrees of freedom; p = 0.51).

Non-Response

Respondents and non-respondents had similar characteristics except for the setting of care and number of acute care visits in the past year. The majority of non-respondents received care at an ED (62%) whereas the majority of respondents received care at an IC (58%), and this difference was statistically significant (p <0.001). Non-respondents had a lower number of acute care visits in the past year compared to respondents (median: 4 vs. 5, p <0.05). (Table 6) Weighted data yielded similar results to our main analyses of unweighted data. Results not shown.

4.5 Discussion

To date, this is the first study to investigate patients' perception of safety among adults with SCD in the acute care setting. In the overall sample, 31% of patients had lower perceptions of overall level of patient safety and 24% of patients perceived to have any specific safety concerns during their acute care visit. Relative to the ED, patients who received care at an IC were significantly less likely to experience lower perceptions of overall level of patient safety. Patients at an IC were less likely to perceive medication errors and mistakes by nurses, and had fewer numbers of specific concerns compared to patients at an ED.

There are several reasons that may explain the association of the setting of care and patients' perception of safety. The IC is less crowded and less noisy than the busy

nature of the ED, and operates on average 8-10 hours per day whereas the ED operates 24 hours of the day. Staff in the IC may be more experienced with pain management, better acquainted with the patient including his/her medical history, and have less workload and pressures relative to ED staff. Related to pain management, differences exist in the average time to receive a first dose of opioid and opioid dose between the ED and IC. [30, 117] Several studies have shown that adults with SCD have reported negative interpersonal experiences and provider attitudes. These negative experiences comprise of providers' stigmatization of SCD and drug seeking behaviors, lack of patient involvement in their care, lower levels of patient trust towards providers, and perception of neglect from clinicians. [24, 25, 118-120] We argue that these factors may contribute to patients' perception of safety, which warrants further investigation.

Patients with SCD are chronically ill patients and are commonly predisposed to acute VOC as part of their illness and to opioid treatment; thus, they may be more likely to perceive medication errors than other errors. Medication errors are one of the most common errors in the ED, [121] which may explain why patients have reported it the most frequent specific concern. There are several factors that may contribute to medication errors in the ED such as unfamiliarity with the patient and patients' medication history, reliance on verbal orders, variety of opioid medications, and ED dispensing, which allows EDs to function as a pharmacy rather than having input from a pharmacist. [121]

Further, mistakes by nurses were one of the most commonly reported specific concerns in this sample, and associated with the setting of care. Nurses are in the frontlines of patient assessment and pain management: they may assess patient vital signs and pain level, administer medication, and prepare patients' discharge. Relative

to other healthcare providers, nurses spend more time with the patient and with monitoring pain relief in adults with SCD. The amount of workload and distractions that nurses experience may contribute to such errors and may overlap with other types of errors as well. [122] In a national study on medication errors in over 400 EDs in the US, nurses were responsible for 54% of errors where the error incidence was 78 reports per 100,000 visits. [122] Emergency nurses also report time pressures, less authority to make decisions, and physical demands, which may also lead to further stress. [123] These factors might be different for nurses in the IC given the different organizational characteristics.

Compared to the general population,[58] patients with SCD reported similar feelings of overall level of patient safety but perceived lower numbers of specific safety concerns. It could be that patients underestimated the number of specific safety concerns due to self-report, inability to categorize their feelings of safety concern, or do not perceive these concerns as often. Patients might have also had different specific concerns that were not mentioned in the survey. However, our sample was more concerned about medication errors and mistakes by nurses than any other specific safety concerns. In a study by Burroughs et al. of general emergency department patients, patients were more concerned about misdiagnosis, followed by mistakes by physicians, medication errors, and mistakes by nurses. We argue that medication errors and mistakes by nurses are most related to acute pain management for acute VOC in adults with SCD.

Several limitations exist in this study. We only included adults with SCD who had access to an ED and IC; thus, results may only be generalizable to adults who have access to these facilities. Response rates could have been higher but was similar to a previous study of patients' perception of safety in the ED. [58] To decrease the

risk of non-response bias, we conducted a sensitivity analysis using weighted data, which yielded similar results of our main analysis. For this analysis, we used cross-sectional data; thus, causal inferences are limited. There could have been other factors that contributed to the associations between the setting of care and medical errors such as shift time and day of the week. [122] There could have been other concerns that were not captured by the survey administered. Most importantly, perception of safety may not always correlate with medical errors documented in the electronic medical records or other reporting systems. [124]

Despite these limitations, this study has important contributions to the literature of patient safety, which has never been explored in the population of SCD. Results from this study may be considered as baseline estimates of patients' perception of safety in adults with SCD in the acute care settings. Our study yields preliminary evidence to the association of setting of care and patients' perception of overall level of patient safety and specific safety concerns, which was conducted in four geographically and clinically diverse sites across the US.

Our results have important implications for safety improvement initiatives and staff education regarding patient safety. Regardless of setting of care, patients perceive safety issues in both the ED and IC. Patients' perception of overall level of patient safety and specific safety concerns, with medication errors and mistakes by nurses being the most common, could be used to educate staff and program safety developers on what concerns they might address to improve the patient experience. Engaging patients in detecting medical errors in a timely manner could be a future goal. Further follow-up with patients who reported a specific concern would be helpful to identify any effects of these concerns, which may have been harmful to the patient.

4.6 Conclusions

Our results demonstrate an association between the setting of care and patients' perception of overall level of patient safety. Medication errors and mistakes by nurses were the two specific safety concerns that were associated with the setting of care, including the number of perceived specific concerns. Patients' perception of safety in adults with SCD could be incorporated in safety improvement initiatives to improve patient safety and overall patient experience. Adoption of the IC model may result in improved patient safety in adults with SCD. Further study is needed to better understand the key factors that may be contribute to patients' perception of safety, other comprehensive safety concerns that adults with SCD might experience, and most importantly ways to improve patient safety in this population.

Table 4.1 Patient characteristics in the overall sample and stratified by emergency department (ED) and infusion center (IC) (N = 205)

Patient characteristic	Overall sample (N = 205)	ED (n = 87)	IC (n = 118)
Age (years), mean (SD)* (Range, 19-79)	33.5 (10.6)	31.2 (9.3)	35.3 (11.3)
Sex (%)			
Female	129 (63%)	56 (64%)	73 (62%)
Male	76 (37%)	31 (36%)	45 (38%)
Graduated high school (%)			
Yes	168 (82%)	70 (80%)	98 (83%)
No	31 (15%)	16 (18%)	15 (13%)
Employed (%)			
Yes	76 (37%)	31 (36%)	45 (38%)
No	128 (62%)	55 (63%)	73 (62%)
Low annual income < $20,000 (%)			
Yes	99 (48%)	44 (51%)	55 (47%)
No	93 (46%)	39 (45%)	54 (46%)
Did not mention	13 (6%)	4 (4%)	9 (7%)
Insured by Medicaid (%)			
Yes	114 (56%)	51 (59%)	63 (53%)
No	86 (42%)	34 (39%)	52 (44%)
SCA (%)			
Yes	139 (68%)	59 (68%)	80 (68%)
No	63 (31%)	26 (30%)	37 (31%)
Pain level at arrival, median (IQR) (Range: 0 – 10)*	9 (8-10)	9 (8-10)	8 (7-10)
Number of acute care visits in the past year, median (IQR) (Range, 0 – 65)	5 (2-12)	5 (2-11)	5 (2-12)

* $p < 0.01$; statistically significant

Note: Some column percentages do not add up due to missing data in the following variables: graduated high school, employed, insured by Medicaid, and SCA

Table 4.2 Patients' perception of overall level of patient safety (N = 205)

Perceived overall level of patient safety	Overall sample N (%)	ED n (%)	IC n (%)
Excellent	84 (41%)	26 (30%)	58 (49%)
Very good	57 (28%)	17 (20%)	40 (34%)
Good	41 (20%)	25 (28%)	16 (14%)
Fair	17 (8%)	14 (16%)	3 (2%)
Poor	6 (3%)	5 (6%)	1 (1%)
Total	205	87	118

Note: p <0.001; Fisher's exact test to compare overall level of patient safety between the ED and IC

Table 4.3 Patients' perception of specific safety concerns

Perceived specific safety concerns	Overall sample N (%)	ED n (%)	IC n (%)
Falling and being injured			
Yes	14 (7%)	9 (10%)	5 (4%)
No	191 (93%)	78 (90%)	113 (96%)
A mistake or error with medications*			
Yes	23 (11%)	16 (18%)	7 (6%)
No	182 (89%)	71 (82%)	111 (94%)
Problems with medical equipment			
Yes	8 (4%)	5 (6%)	3 (3%)
No	197 (96%)	82 (94%)	115 (97%)
A mistake by nurses*			
Yes	22 (11%)	18 (21%)	4 (3%)
No	183 (89%)	69 (79%)	114 (97%)
A mistake by physicians			
Yes	10 (5%)	7 (8%)	3 (3%)
No	195 (95%)	80 (92%)	115 (97%)
Being mistaken for another patient			
Yes	7 (3%)	3 (3%)	4 (3%)
No	198 (97%)	84 (97%)	114 (97%)
Wrong test/procedure			
Yes	10 (5%)	7 (8%)	3 (3%)
No	195 (95%)	80 (92%)	115 (97%)
Would be misdiagnosed			
Yes	19 (9%)	11 (13%)	8 (7%)
No	186 (91%)	76 (87%)	110 (93%)
Total	205	87	118

* $p < 0.05$ *using Fisher's exact test* to compare each perceived specific safety concern between the ED and IC

Table 4.4 Odds ratios (OR) and 95% confidence intervals (CI) for the association between the setting of care and each specific safety concern

Perceived specific safety concerns	Unadjusted OR (95%CI)
Falling and being injured	0.38 (0.12 – 1.19)
A mistake or error with medications	0.28 (0.11 – 0.71) *
Problems with medical equipment	0.43 (0.10 – 1.84)
A mistake by nurses	0.13 (0.04 – 0.41) **
A mistake by physicians	0.30 (0.07 – 1.19)
Being mistaken for another patient	0.98 (0.21 – 0.45)
Wrong test/procedure	0.30 (0.07 – 1.19)
Would be misdiagnosed	0.50 (0.19 – 1.31)

$*p < 0.01$; $**p < 0.001$

Table 4.5 Incidence rate ratios (IRR) and 95% confidence intervals (CI) for the association between the setting of care and number of specific safety concerns

	Model 1	Model 2	Model 3	Model 4
IC vs. ED	0.36 (0.19 – 0.69)*	0.38 (0.20 – 0.72)*	0.38 (0.20 – 0.73)*	0.37 (0.19 – 0.72)*
Age (years)		0.98 (0.95 – 1.01)	0.98 (0.95 – 1.01)	0.98 (0.95 – 1.01)
Gender (ref: men)		1.55 (0.80 – 2.99)	1.64 (0.84 – 3.19	1.64 (0.84 – 3.19)
Pain level on arrival			1.11 (0.87 – 1.41)	1.08 (0.85 – 1.37)
Number of acute care visits			1.00 (0.96 – 1.03)	1.00 (0.97 – 1.04)
Mode of survey administration (ref: interviewer-administered)				0.59 (0.30 – 1.14)

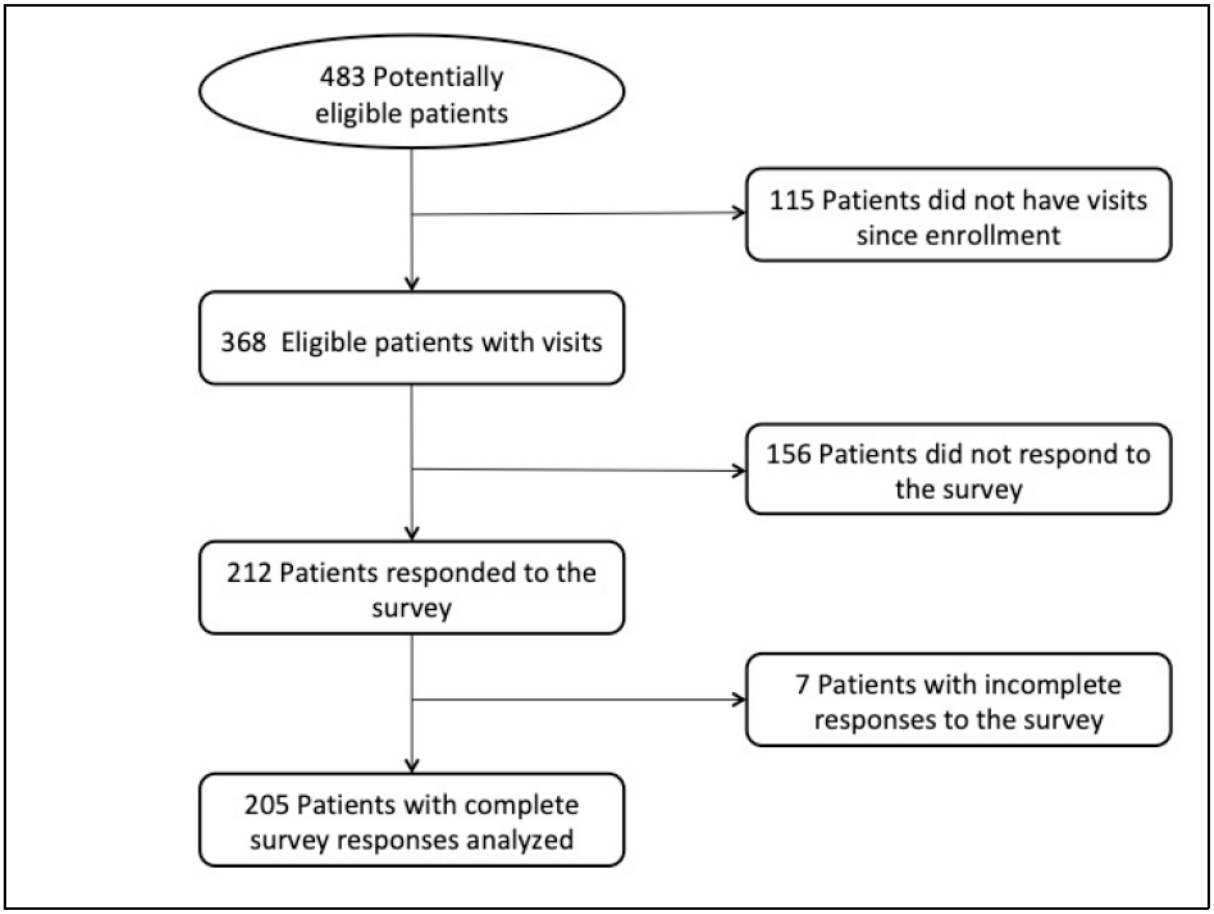
*p <0.01; statistically significant
ref: reference category

Table 4.6 Comparison between respondents and non-respondents (N=368)

Patient characteristic	All eligible participants (N=368)	Respondents (n = 205)	Non-respondents (n=162)
Place of visit (%)*			
ED	188 (51%)	87 (42%)	100 (62%)
IC	179 (49%)	118 (58%)	62 (38%)
Age (yrs), mean (SD) (Range: 19-79)	33.9 (10.7)	33.5 (10.6)	34.4 (10.9)
Sex (%)			
Female	224 (61%)	129 (63%)	95 (59%)
Male	143 (39%)	76 (37%)	67 (41%)
Graduated high school (%)			
Yes	294 (80%)	168 (82%)	126 (78%)
No	61 (17%)	31 (15%)	30 (19%)
Employed (%)			
Yes	133 (36%)	76 (37%)	57 (35%)
No	230 (63%)	128 (62%)	102 (63%)
Low annual income < $20,000 (%)	179 (49%)	99 (48%)	80 (49%)
Yes	168 (46%)	93 (46%)	75 (46%)
No	20 (5%)	13 (6%)	7 (4%)
Did not mention			
Insured by Medicaid (%)			
Yes	204 (56%)	114 (56%)	90 (56%)
No	150 (41%)	86 (42%)	64 (40%)
SCA (%)			
Yes	253 (69%)	139 (68%)	114 (70%)
No	104 (28%)	63 (31%)	41 (25%)
Pain level at arrival, median (IQR) (Range: 0 – 10)	9 (8-10)	9 (8-10)	9 (8-10)
Number of acute care visits, median (IQR) (Range: 0 – 90)**	4 (2-11)	5 (2-12)	4 (1-9)

*p <0.001, **p <0.05

Figure 4.1 Patient flow process overview



CHAPTER 5. CONCLUSIONS

5.1 Summary of Principal Findings

In this dissertation, the main goal was to examine the associations between the setting of care (ED or IC) and patient-centered outcomes: 1) patient satisfaction with pain management, including psychometric evaluation of this measure, and 2) patients' perception of safety after the treatment of an acute VOC. All three studies used a cross-sectional analysis of first time visits within a multisite longitudinal prospective cohort study of adults with SCD being treated for an acute VOC.

In the first study, a psychometric evaluation of the **P**atient **S**atisfaction with **P**ain Management in Adults with **S**CD (PSPS) scale was conducted. The PSPS was designed to assess patient satisfaction with pain management after the treatment of an acute VOC in the acute care setting (the ED and IC). The PSPS showed evidence of internal construct validity: exploratory factor analysis revealed a single factor that was represented by 15 survey items. The PSPS showed evidence of external construct validity: the mean PSPS score was positively correlated with a safety measure of global safety in the acute care setting and inversely correlated with the number of concerns patients reported during their stay. The scale also had high internal consistency reliability.

In the second study, I used structural equation modeling to examine the association between the setting of care (the ED or IC) and adult patients' satisfaction with pain management using the PSPS scale, controlling for demographic and clinical characteristics. Results show that receiving care at an IC is statistically significantly associated with higher levels of satisfaction with pain management compared to receiving care at an ED after controlling for age, sex, chronic pain, pain level on arrival, acute care utilization in the past year, and mode of survey administration.

These results suggest that the IC, relative to the ED, may provide better pain management as evidenced by patients' satisfaction with pain management.

In the third study, I examined the association between the setting of care (ED or IC) and patients' perception of safety during an acute care visit for the treatment of an acute VOC among adults with SCD. Patients who received care in the IC had statistically significantly lower odds of lower perceptions of overall level of patient safety, medication errors, and mistakes by nurses. There was no statistically significant association between the setting of care and falling and being injured, problems with medical equipment, mistakes by physicians, being mistaken for another patient, wrong test/procedure, and misdiagnosis. Further, there were fewer numbers of specific concerns perceived in patients who received care at an IC compared to patients who received care at an ED. These results suggest areas for quality and safety improvement efforts in both the ED and IC. Adoption of the IC model may result in improved perceptions of patient safety in adults with SCD.

5.2 Implications in Policy and Practice

The findings of this dissertation have important contributions to the literature of quality of care in adults with SCD with a focus on patient-centered care. Adults with SCD do not receive the quality of care they need when being treated for an acute VOC, which is traditionally delivered in the ED. Patients are often dissatisfied with quality of pain management and are concerned about their safety in the ED, which reflects the lack of patient-centered care. An IC is an alternative model of care for acute pain management in adults with SCD. However, they are not readily available nor are they accessible to all subpopulations in the US. While some studies have shown benefits of IC compared to the ED, there has been a lack of studies that

integrate the patient voice to assess the association of these settings of care with patient-centered outcomes. The American Society of Hematology along with other organizations have endorsed these issues as priorities in the most recent annual conference in December 2018. Therefore, it is crucial to provide evidence on how patient-centered outcomes differ across the ED and IC to be able to achieve patient-centered care in adults with SCD.

From a research and practice perspective, our findings of internal and external construct validity and internal consistency reliability of the PSPS scale provides a sound and reliable measurement of patient satisfaction with pain management in adults with SCD in the acute care setting. Validity is a continuous process that requires further evidence for improving the measurement structure of this scale such as reducing further items to make it easier to administer for clinical purposes or adding further items that are specific to pain dose and frequency of pain medication and assessment. With further testing, the PSPS could be helpful for studying the impact of quality improvement interventions on patient satisfaction with pain management. Further studies are needed to test the PSPS in other SCD populations and in other geographic regions, to assess sensitivity to change in a longitudinal analysis, to study the association between satisfaction and different processes of care (time to first dose and time to reassess pain) to be able to modify or target interventions to improve patient satisfaction, and to study the link between satisfaction and other outcomes or measures such as quality of life and hospital admissions to be able to demonstrate the clinical significance of this scale.

Findings of this dissertation shed light on how the IC vs. the ED may be associated with patient satisfaction with pain management and patients' perception of safety in adults with SCD. Patients in the IC are more satisfied about their pain

management and feel safer than patients in the ED. Furthering our knowledge on the benefits of the IC relative to the ED, this dissertation puts the patient in the center of providing evidence of quality of care perceived in different acute care settings. Further studies are needed to test the impact of ICs on these measures over time and to control for system-level factors that may affect the relationship between the setting of care and patient-centered outcomes.

Further, findings on patients' perception of safety after the treatment of an acute VOC may help researchers, clinicians, and program developers to understand the different patient safety issues. The novelty of these findings suggests that patients are able to recognize and report safety issues, which highlights areas for quality and patient safety improvement efforts. While more research is needed to unravel the causes of lower perceptions of overall patient safety and perceptions of specific safety concerns, this research may be a starting point for further exploration. Further qualitative studies are needed to help understand how patients with SCD perceive patient safety, what other patient concerns may be of importance to these patients, and the extent of patients' willingness to be involved in improving patient safety.

From a policy and clinical perspective, this dissertation may help inform policy developers, healthcare systems, and clinicians to address the differences in patient-centered outcomes in adults with SCD. Although further evidence of causation is needed, this dissertation's principal findings may aid in increasing availability of IC and improving access to these centers, and improving the quality of care in the ED. Although beyond the scope of this dissertation and an area for further research, interventions that aim to improve patient-centered outcomes in the acute care settings are needed to improve the quality of care, which may be related to increased quality of life and life expectancy in adults with SCD.

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Appendix A. Survey Instrument

Survey:

Thank you again for participating. Please remember that all of your responses will be kept confidential. Please answer each question as honestly as possible (Choose one response only). Please indicate how strongly you agree or disagree with each of the following statements by marking the circle that best fits how you feel.

Study ID:

1. The staff adequately assessed your pain	◯ Very Strongly Disagree ◯ Strongly Disagree ◯ Disagree ◯ Uncertain ◯ Agree ◯ Strongly Agree ◯ Very Strongly Agree
2. You received treatment in a timely manner	◯ Very Strongly Disagree ◯ Strongly Disagree ◯ Disagree ◯ Uncertain ◯ Agree ◯ Strongly Agree ◯ Very Strongly Agree
3. The staff adequately responded to your pain	◯ Very Strongly Disagree ◯ Strongly Disagree ◯ Disagree ◯ Uncertain ◯ Agree ◯ Strongly Agree ◯ Very Strongly Agree
4. You were satisfied with the communication with the nurses	◯ Very Strongly Disagree ◯ Strongly Disagree ◯ Disagree ◯ Uncertain ◯ Agree ◯ Strongly Agree ◯ Very Strongly Agree
5. Your nurse believed your reports about your pain	◯ Very Strongly Disagree ◯ Strongly Disagree ◯ Disagree ◯ Uncertain ◯ Agree ◯ Strongly Agree ◯ Very Strongly Agree
6. You were satisfied with the communication with the physicians	◯ Very Strongly Disagree ◯ Strongly Disagree ◯ Disagree ◯ Uncertain ◯ Agree ◯ Strongly Agree ◯ Very Strongly Agree
7. Your doctor believed your reports about your pain	◯ Very Strongly Disagree ◯ Strongly Disagree ◯ Disagree ◯ Uncertain ◯ Agree ◯ Strongly Agree ◯ Very Strongly Agree

8. The doctor told me all I wanted to know about my illness
- ○ Very Strongly Disagree
- ○ Strongly Disagree
- ○ Disagree
- ○ Uncertain
- ○ Agree
- ○ Strongly Agree
- ○ Very Strongly Agree

9. The doctor seemed interested in me as a person
- ○ Very Strongly Disagree
- ○ Strongly Disagree
- ○ Disagree
- ○ Uncertain
- ○ Agree
- ○ Strongly Agree
- ○ Very Strongly Agree

10. The doctor seemed warm and friendly to me
- ○ Very Strongly Disagree
- ○ Strongly Disagree
- ○ Disagree
- ○ Uncertain
- ○ Agree
- ○ Strongly Agree
- ○ Very Strongly Agree

11. The doctor seemed to take my problems seriously
- ○ Very Strongly Disagree
- ○ Strongly Disagree
- ○ Disagree
- ○ Uncertain
- ○ Agree
- ○ Strongly Agree
- ○ Very Strongly Agree

12. I really felt understood by my doctor
- ○ Very Strongly Disagree
- ○ Strongly Disagree
- ○ Disagree
- ○ Uncertain
- ○ Agree
- ○ Strongly Agree
- ○ Very Strongly Agree

13. This is a doctor I would trust with my life
- ○ Very Strongly Disagree
- ○ Strongly Disagree
- ○ Disagree
- ○ Uncertain
- ○ Agree
- ○ Strongly Agree
- ○ Very Strongly Agree

14. The doctor seemed to know what (s) he was doing
- ○ Very Strongly Disagree
- ○ Strongly Disagree
- ○ Disagree
- ○ Uncertain
- ○ Agree
- ○ Strongly Agree
- ○ Very Strongly Agree

15. The doctor has relieved my worries about my illness
- ○ Very Strongly Disagree
- ○ Strongly Disagree
- ○ Disagree
- ○ Uncertain
- ○ Agree
- ○ Strongly Agree
- ○ Very Strongly Agree

16. The doctor seemed to know just what to do for my problem

- ◯ Very Strongly Disagree
- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Uncertain
- ◯ Agree
- ◯ Strongly Agree
- ◯ Very Strongly Agree

17. You are satisfied with the treatment you received for your pain

- ◯ Very Strongly Disagree
- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Uncertain
- ◯ Agree
- ◯ Strongly Agree
- ◯ Very Strongly Agree

18. Overall, you are satisfied with the quality of care you received

- ◯ Very Strongly Disagree
- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Uncertain
- ◯ Agree
- ◯ Strongly Agree
- ◯ Very Strongly Agree

19. During your visit you were allowed to participate in decisions about your pain treatment as much as you wanted to?

- ◯ Very Strongly Disagree
- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Uncertain
- ◯ Agree
- ◯ Strongly Agree
- ◯ Very Strongly Agree

20. Your pain was adequately controlled

- ◯ Very Strongly Disagree
- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Uncertain
- ◯ Agree
- ◯ Strongly Agree
- ◯ Very Strongly Agree

21. You received enough medication/treatment to deal with my pain

- ◯ Very Strongly Disagree
- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Uncertain
- ◯ Agree
- ◯ Strongly Agree
- ◯ Very Strongly Agree

22. The provider ensured that you had enough pain medication to manage your pain at home

- ◯ Very Strongly Disagree
- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Uncertain
- ◯ Agree
- ◯ Strongly Agree
- ◯ Very Strongly Agree

23. What went well during this acute visit? _____

24. What did not go well? _____

25. Did you come to the ED/Infusion clinic by yourself today?

- ◯ Yes
- ◯ No

26. If you brought someone with you was it because; (CHECK ALL THAT APPLY):

- ☐ You could not get here without help because you were too sick
- ☐ You could not get here by yourself because of transportation issues
- ☐ Your companion acts as your advocate while you are receiving care
- ☐ Your companion helps make sure you get the treatment you need
- ☐ Your companion keeps you company while you are being treated
- ☐ Other

If Other, Specify _____

27. Bringing someone with me when I am in the ED/Infusion clinic helps improve the quality of care I receive

- ◯ Very Strongly Disagree
- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Uncertain
- ◯ Agree
- ◯ Strongly Agree
- ◯ Very Strongly Agree

28. Please rate the overall level of medical safety (defined as "freedom from any medical error or mistake") you felt during your acute stay.

- ◯ Excellent
- ◯ Very good
- ◯ Good
- ◯ Fair
- ◯ Poor

29. During your acute visit, were you ever concerned that any of the following would occur (CHECK ALL THAT APPLY):

	Yes	No
Falling and being injured	☐	☐
A mistake or error with medications	☐	☐
Problems with medical equipment	☐	☐
A mistake by nurses	☐	☐
A mistake by physicians	☐	☐
Being mistaken for another patient	☐	☐
Wrong test/procedure	☐	☐
Would be misdiagnosed	☐	☐

Date of survey completion _____

Is survey administered by:

- ◯ Phone
- ◯ In person
- ◯ Computer

Appendix B. Odds ratios and 95% confidence intervals for the association between place of acute care visit and perception of overall patient safety (Fair/poor vs. excellent/very good/good)

	Model 1	Model 2
IC vs. ED	0.13 (0.08 – 0.19)*	0.13 (0.04 – 0.41)*
Age (years)		0.99 (0.94 – 1.04)
Gender (men)		3.06 (1.18 – 7.99)*
Pain level on arrival		1.19 (0.82 – 1.73)
Number of acute care visits in the past year		1.03 (0.99 – 1.06)

* p <0.05; statistically significant

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Bachelor in Medicine and Surgery (MBBS) [07/2009]
Faculty of Medicine, King Abdulaziz University, Jeddah, KSA

Academic Experience

Research Assistant [06/2016 – 05/2019]
Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, US

Teaching Assistant [09/2016; 09/2017; 09/2018]
Quality of Medical Care course
Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, US

Lecturer [06/2017]
Quality of Medical Care course
Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, US

Lecturer [01/2017; 01/2018]
Research Principles and Methodology for Trainees
Faculty of Medicine, King Abdulaziz University, Jeddah, KSA

Teaching Assistant [07/2014; 07/2015]
From Bench to Bedside: Research Training Course
Johns Hopkins Medical Institutions, Baltimore, MD, US

Postdoctoral Research Fellow [07/2014 – 08/2015]
Department of Gynecology and Obstetrics, Johns Hopkins University, Baltimore, MD

Teaching Assistant [08/2011 – Present]
Department of Medical Education, King Abdulaziz University, Jeddah, KSA

Lecturer [11/2011]
Student Advocacy Lectures
Department of Medical Education, King Abdulaziz University, Jeddah, KSA

Facilitator [12/2011]
Towards More Integration Hands-on Workshop
Department of Medical Education, King Abdulaziz University, Jeddah, KSA

Facilitator [12/2011]
Problem-Based Learning Workshop
Department of Medical Education, King Abdulaziz University, Jeddah, KSA

Facilitator [09/2011]
Essential Skills for Clinical Simulation Instructing Course
Department of Medical Education, King Abdulaziz University, Jeddah, KSA

Clinical Experience

Medical Resident [10/2010 - 06/2011]
Department of Gynecology & Obstetrics, King Fahd Armed Forces Hospital

Rotating Intern [08/2009 - 07/2010]
Family and Community medicine, Obstetrics & Gynecology, Internal Medicine, Surgery and Pediatrics
King Abdulaziz University Hospital

Summer Training
Pediatrics – Ampang Puteri Hospital, Kuala Lumpur, Malaysia [08/2008]
Rheumatology – Tawakal Specialist Hospital, Kuala Lumpur, Malaysia [07/2008]

Awards & Honors

King Abdulaziz University Scholarship for Postgraduate Studies in Public Health – Doctoral Degree [06/2015]
Deanship of Graduate Studies, King Abdulaziz University, Jeddah, KSA

Membership of the Alpha Chapter of the Delta Omega Society [05/2014]
Public Health Honorary Society, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

Best Innovative Intervention

"Add Another Voice: Make a Call for Her" [10/2013]
Department of Health, Behavior and Society, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

King Abdulaziz University Scholarship for Postgraduate Studies in Public Health – Masters Degree [05/2013]
Deanship of Graduate Studies, King Abdulaziz University, Jeddah, KSA

Presentations

Patient Satisfaction with Pain Management in Emergency Departments and Adults Sickle Cell Infusion Centers [02/2019]
Center for Health Services and Outcomes Research, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, US

Patient Satisfaction of Care in the Treatment of Vaso-Occlusive Crises: A Comparison of Emergency Department and Infusion Centers in the ESCAPED Study [12/2018]
Presented at the 60th American Society of Hematology (ASH) Annual Meeting and Exposition
Selected as 2019 Highlights of ASH

Pain Experiences of Adults with Sickle Cell Disease After Bone Marrow Transplant: A Qualitative Study [9/2018, 10/2018]
Presented at Sickle Cell Improvement across the North East Region through Education (SiNERGe) meetings at the Johns Hopkins Hospital
Presented at the Center of Qualitative Studies in Health & Medicine

Patients' Perspectives on Quality of Serious Illness Care in Primary Care [03/2018]
Presented at the Annual Assembly of the American Academy of Hospice and Palliative Medicine (AAHPM)

A Survey to Evaluate Facilitators and Barriers to Quality Measurement and Improvement: Adapting Tools for Implementation Research in Palliative Care Programs [03/2018]
Presented at the Annual Assembly of the American Academy of Hospice and Palliative Medicine (AAHPM)

Patients' Perspectives on Implementing Advance Care Planning Initiatives in Outpatient Settings [12/2016; 11/2016]
Presented at the 9th Annual Conference on the Science of Dissemination and Implementation Presented at the Welch Grand Rounds at the Johns Hopkins Bloomberg School of Public Health

Resource Utilization and Factors for Increased Cost of Hospitalization for Asthma in the United States [04/2015]
Presented at Pediatric Academic Societies Annual Meeting

What Should an MFM Do With an Abnormal Umbilical Artery Doppler (UAD) Study in a Normally Grown Fetus? [02/2015]
Presented at the Society for Maternal Fetal Medicine Pregnancy Meeting

Publications

Abu Al Hamayel, N., Isenberg, S. R., Sixon, J., Smith, K. C., Pitts, S. I., Dy, S. M & Hannum, S. M. (Pending). Preparing Older Patients with Serious Illness for Advance Care Planning Discussions in Primary Care. *Journal of Pain and Symptom Management*.

Dy, S. M., Sharma, R., Kuchinad, K., Liew, Z. R., **Abu Al Hamayel, N.**, Hannum, S. M., ... & Isenberg, S. R. (2018). Evaluation of the Measuring and Improving Quality in Palliative Care Survey. *Journal of oncology practice*, *14*(12), e834-e843.

Abu Al Hamayel, N., Isenberg, S. R., Hannum, S. M., Sixon, J., Smith, K. C., & Dy, S. M. (2018). Older Patients' Perspectives on Quality of Serious Illness Care in Primary Care. *American Journal of Hospice and Palliative Medicine®*, 1049909118771675.

Dy, S. M., Isenberg, S. R., & **Al Hamayel, N. A.** (2017). Palliative Care for Cancer Survivors. *Medical Clinics*, *101*(6), 1181-1196.

Dy, S. M., **Al Hamayel, N.A,** Hannum, S. M., Sharma, R., Isenberg, S. R., Kuchinad, K., ... & Walling, A. M. (2017). A Survey to Evaluate Facilitators and Barriers to Quality Measurement and Improvement: Adapting Tools for Implementation Research in Palliative Care Programs. *Journal of Pain and Symptom Management*, *54*(6), 806-814.

Tsimis, M. E., **Al-Hamayel, N. A.**, Germaine, H., & Burd, I. (2015). Prematurity: present and future. *Minerva ginecologica*, *67*(1), 35.

Alahwal, H. M. S., Al Sayes, F., El-deek, B. S., Kurdi, B., **Al-Hamayel, N. A.**, & Barefah, A. S. (2010). Career counseling activities and choice of specialties among medical interns. *Bahrain Med Bull*, *32*(4), 1-7.

Professional Memberships

American Society of Hematology [Since 09/2018]
American Academy of Hospice and Palliative Medicine [Since 01/2017]
Academy Health [Since 09/2016]
Alpha Chapter of Delta Omega Public Health Honorary Society [Since 05/2014]
American Public Health Association [Since 10/2013]

Added Qualifications

Primary level of French language proficiency:

Alliance Francaise, Accra, Ghana [07 - 09/2005]
Center Franco-Saoudien, Jeddah
40 Hours. Level A1.1 [12/2009 - 02/2010]
40 Hours. Level A1.2 [02/2010 - 04/2010]
40 Hours. Level A1.3 [04/2010 - 06/2010]

Arabic native speaker

Statistical analysis using STATA software (Data management and analysis) proficiency

Qualitative data analysis using MAXQDA12 software (Data management and analysis) proficiency

Interests & Hobbies

Creative and free writing, photography, artwork, and fitness